EXHIBIT G

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC, REPAIR SYSTEM PRODUCTS, LIABILITY LITIGATION	MASTER FILE NO. 2:12-MD-02327
	MDL NO. 2327
THIS DOCUMENT RELATES TO CAROLYN LEWIS, ET AL. V. ETHICON, INC. CASE NO. 2:12-CV-04301	JOSEPH R. GOODWIN US DISTRICT JUDGE

FRIDAY, NOVEMBER 15, 2013

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Deposition of Prof. Dr. Med. Uwe Klinge, Volume II, held at the Quellenhoff Hotel, Monheimsallee 52, 52062 Aachen, Germany, commencing at 8:35 a.m., on the above date, before Carrie A. Campbell, Registered Professional Reporter, Certified Realtime Reporter, Certified Shorthand Reporter, and Certified Court Reporter.

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GOLKOW TECHNOLOGIES, INC.
877.370.3377 ph|917.591.5672 fax
deps@golkow.com

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EXHIBITS

APPEARANCES:

ANDERSON LAW OFFICES, LLC
BY: BENJAMIN HOUSTON ANDERSON, ESQUIRE
ben@andersonlawoffices.net
1360 West 9th Street, Suite 215
Cleveland, Ohio 44113
(216) 592-8384

AYLSTOCK, WITKIN, KREIS & OVERHOLTZ, PLLC
BY: DANIEL J. THORNBURGH, ESQUIRE
dthornburgh@awkolaw.com
17 East Main Street, Suite 200
Pensacola, Florida 32502
(850) 202-1010
Counsel for Plaintiffs

THOMAS COMBS & SPANN, PLLC
BY: DAVID B. THOMAS, ESQUIRE
dthomas@tcspllc.com
PHILIP J. COMBS, ESQUIRE
pcombs@tcspllc.com
300 Summers Street, Suite 1380
Charleston, West Virginia 25301
(304) 414-1807

ALSO PRESENT:
Julie Filarski, Anderson Law Offices, LLC

(Klinge Exhibit 12 marked for identification.)

MR. THOMAS: Before the deposition, I told Mr. Anderson during the inquiry yesterday about the redacted exhibit concerning the meeting in Suvretta in 2003. I've been advised that the company has already produced an unredacted copy of that document in another production. I've asked for it and hope to have it when they wake up. So I'll produce it to you as soon as I have it.

MR. ANDERSON: Thank you for doing that.

DIRECT EXAMINATION (Witness previously sworn)

QUESTIONS BY MR. THOMAS:

Q. Doctor, when we closed yesterday, we were talking about who a doctor could consult with to understand the risks related to the using of mesh for the treatment of stress urinary incontinence.

Do you recall that?
A. Yes.
Q. And I believe you identified for me an organization in Germany that you called the AWMF; is that correct?
A. Yes.
Q. Let me show you what I've marked as Exhibit Number 12. As I understand it from those people who looked for me, Exhibit Number 12 is an English version and the short version of the AWMF registry for the diagnosis and treatment of stress urinary incontinence in women.
Is that fair?
MR. ANDERSON: Objection.
QUESTIONS BY MR. THOMAS:
Q. Are you familiar with this document, Doctor?
A. With this English, no, I never read it.
(Klinge Exhibit 13 marked for identification.)
QUESTIONS BY MR. THOMAS:
Q. Let me hand you what's been

marked as Exhibit Number 13. It's the long version, and it's in German.
Do you recognize that document?
MR. ANDERSON: Well, objection. This is a 62-page document and if you want to ask him if he has -- if by the cover of this or he can read 62 pages.
MR. THOMAS: All I want to know, Ben, is whether this is the organization that he discussed yesterday consulting online for the guidelines for the treatment of stress urinary incontinence. I don't want him to read the whole document. We don't have time to do that.
MR. ANDERSON: Different question.
Is this AWMF the organization that you mentioned yesterday as far as you can tell?
THE WITNESS: Yes. I mentioned this.
QUESTIONS BY MR. THOMAS:
Q. And did you consult the

guidelines that you discussed yesterday online on the computer?
A. Please, I had to look, sorry.
Q. I am sorry.
When you referred to the AWMF guidelines --
A. Yeah.
Q. -- did you go to the computer to consult the computer to find those guidelines?
A. When I hadn't looked to this, yes.
Q. Do you have a hard copy of the guidelines from the computer?
A. No.
Q. All right. Do you know whether Exhibit 13 are the guidelines that you looked at online?
A. I tried to figure out the date of when these guidelines have been finished because I know that there are at least two different versions; an older version and a more actual version there. And, therefore, yesterday I mentioned this phrase that has

been changed in the documents I saw when I made my research. It's somewhere in the text. If you like, I can try to find it here, but it's the recommendation of surgical therapy.
Q. Okay. I don't want to do that.
A. So I'm not sure whether this is the last version here.
Q. That's fine.
(Klinge Exhibit 14 marked for identification.)
QUESTIONS BY MR. THOMAS:
Q. Let me hand you what's been marked now as Deposition Exhibit Number 14. Deposition Exhibit Number 14, Dr. Klinge, is a document titled "EAU Guidelines on the Surgical Treatment of Stress Urinary Incontinence."
Simple question, have you seen this document before?
A. No, I've not seen it.
Q. And the date on it is September the 7th, 2012, when it was accepted and published online on September the 17th, 2012;

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is that correct? On the left right in the middle?
A. Yeah. That's correct.
Q. Are you familiar with the European Association of Urology?
A. No.
(Klinge Exhibit 15 marked for identification.)
QUESTIONS BY MR. THOMAS:
Q. Let me show you what's been marked as Deposition Exhibit Number 15.
Exhibit Number 15 is a document titled Guidelines on Urinary Incontinence, Text Update, March 2013. It reads, "This pocket version aims to synthesize the important clinical messages described in the full text and is presented as a series of evidence summaries and graded action-based recommendations which follow the standard for levels of evidence used by the EAU."
Have you seen Exhibit Number 15 before today?
A. No, I haven't seen it.
Q. Doctor, are you familiar with

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an organization known as the American Urological Association?
A. Familiar, if you mean that I have ever heard of it or noticed it, I think so, yes.
Q. Do you consider the American Urological Association to be authoritative in the field of stress urinary incontinence treatment?
MR. ANDERSON: Objection. Dr. Klinge is not a urologist and he's not here being offered as a urologist nor the treatment options of SUI, and as I stated yesterday, and so all of these questions about treatment recommendations for a urologist or a urogynecologist clearly are outside of the scope of his expert report and the reasons that he's being offered as an expert. If counsel wants to continue to ask questions about it, but I'm going to move to strike all of it.
QUESTIONS BY MR. THOMAS:
Q. Do you consider the American

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Urological Association to be authoritative in the field of treatment of stress urinary incontinence?
A. I cannot comment on this. I know from my colleagues here that there are various societies taking care of the problem of incontinence and they're competing. They're sometimes with -- conflicting with different assumptions, different advices or less.
To my knowledge from all of the discussions with them, there is not one single society that is authoritative, yeah, that is able to give recommendations for the woman either treated by urologist or gynecologist. But, of course, you find a lot of these different societies. Maybe this is an expression that there are different opinions as well.
Q. And you said, "I know from my colleagues here." Is that conversations that you've had with colleagues at the hospital where you work?
A. Yes. We have a close

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collaboration with Professor Kirschner-Hermanns, for example, she has been the leader of the incontinence center.
Q. And that's the incontinence center at the hospital that's part of the university?
A. Yeah.
(Klinge Exhibit 16 marked for identification.)
QUESTIONS BY MR. THOMAS:
Q. Let me show you what's been marked as Deposition Exhibit Number 16. This is titled "Position Statements of the American Urological Association." It's dated at the bottom November 2011.
Is it fair to understand that you've not seen this position statement of the American Urological Association?
MR. ANDERSON: Same objections I stated before.
THE WITNESS: I don't recall whether this is exactly. I recall that I have seen some recent position statements by some of these societies,

but it's not my focus to list all of these various societies and various aspects.

(Klinge Exhibit 17 marked for identification.)

QUESTIONS BY MR. THOMAS:

Q. Let me show you what I've marked now Deposition Exhibit Number 17.

Deposition Exhibit Number 17 is from the American Urogynecologic Society, and it's titled "Position Statement on Restriction of Surgical Options for Pelvic Floor Disorders."

Have you seen Exhibit 17 before?

A. Maybe. I'm not sure.

Q. Did you consider the position of the American Urogynecologic Society in the formation of your opinions in this case?

MR. ANDERSON: Objection. Same objection before.

THE WITNESS: Please, can you say it again?

QUESTIONS BY MR. THOMAS:

Q. Did you consider the position of the American Urogynecologic Society in the formation of your opinions in this case?

MR. ANDERSON: Objection. The question is not fair.

Do you want him to read the entire document because how could he know whether he considered the position if he doesn't know what it is. My objection stands. He's not going to be asked any of these questions and you know that and it's not anywhere in his report nor is it in his reliance materials, but if you want to keep asking, please, feel free to.

MR. THOMAS: Thank you, I will. I have a limited amount of time here.

MR. ANDERSON: You do.

MR. THOMAS: You can have a standing objection to that.

(Klinge Exhibit 18 marked for identification.)

QUESTIONS BY MR. THOMAS:

Q. Doctor, are you familiar with the International Incontinence Society?

A. Yes. I know them.

Q. Let me hand you what's been marked as Deposition Exhibit Number 18. Deposition Exhibit Number 18 is titled "ICS Fact Sheets, A Background to Urinary and Fecal Incontinence," prepared by the publications and communications committee, July 2013.

Have you seen this document before?

A. Not as a printout version, but I repeatedly am going to the website because they offered a lot of interesting tools for making research and how to investigate all these. So it's an interesting website from the society.

Q. Do you --

A. And among this, there is -- I made a lot of downloads from the society.

Q. Why did you do that?

A. Because I'm interested. I want

to be informed of what happens. There's so many contradicting information and to get an overview, yeah, I'm a scientist and, therefore, it is my duty to go into the problems.

Q. Let's go --

A. To try to learn of it.

Q. Let's go to page 13 of Exhibit 18, please.

On the left side, the second full half reads, "Definitive therapy for SUI is surgical and involves restoring urethral support through use of a sling. Worldwide mid-urethral slings comprised of synthetic mesh have become the treatment of choice for SUI. Long-term data are robust and demonstrate durable efficacy and a very low complication rate particularly in experienced hands."

Do you agree with that statement of the ICS?

MR. ANDERSON: Same objections.

THE WITNESS: The -- I don't think that I'm -- in the moment that

I'm able to give an opinion in what woman, at what stage of the disease, what therapy may be the best.

When they said here they are a low complication rate, we talked about what does it mean low, can we be sure that it is low, that is a question we can have intense discussions about it.

My topic or my -- so far as I understood, my question was whether the use of the Prolene®, when it is coming to complications, whether this is a problem of the material. Whether there are some basic requirements that makes it imperative to use the most heaviest weight mesh from a hernia surgery for the use of this. That was the question that I wanted to address by looking all these things.

So even if there is only one patient with a complication that is not necessary because of using the wrong requirements, that was the question that I wanted to address.

But I'm not able to say their requirements for the societies or so. And I have no doubt that there are some patients taking a big benefit by the use of slings.

(Klinge Exhibit 19 marked for identification.)

QUESTIONS BY MR. THOMAS:

Q. Let me hand you what I've marked now as Deposition Exhibit Number 19. Deposition Exhibit Number 19 --

A. Yeah, that is the NICE, yeah, the National Institute.

Q. Is NICE -- it's called -- it's titled "Urinary Incontinence, the Management of Urinary Incontinence in Women," issued September 2013. And it's issued by the organization called NICE, the National Institute For Health and Care Excellence.

Is this the document to which you referred yesterday in your testimony?

A. I downloaded, if I remember correctly, about 10, 15 documents from the website from NICE. So this is one of it.

Q. Why did you go to the NICE website?

A. Same answer as some minutes before; to get informed the search and literature is one of our most important tools and -- there has been -- in February -- last year the question whether we have access to all of these things and I would like to point out that at the university we have an almost unlimited access to all things that are published there to correct this impression that it is restricted to the journals I get personally.

Q. I didn't suggest that.

A. No, it was from the last year or in February there has been the discussion, there has been the question whether do our -- getting these specific journal and I just wanted to take this opportunity to clarify that we have huge possibilities to access.

Q. I understand that.

The computer is a wonderful thing, isn't it?

A. It has changed completely our

work.

Q. Doctor, let's go back to your report, please, which is Exhibit Number 11.

On page 2 of Exhibit 11 under the summary of your opinions, you say, "The mesh -- excuse me, the Prolene® mesh in TVT® is a heavy-weight mesh --

MR. ANDERSON: Can you show us where you are?

MR. THOMAS: Right at the top of the page.

MR. ANDERSON: Thank you.

QUESTIONS BY MR. THOMAS:

Q. Doctor, in page 2 of Exhibit 11, you state in your report under the heading, "The Prolene® mesh in TVT® is a heavy-weight mesh ('over engineered').

In that paragraph, you say, "Any pelvic mesh designed with this much excess surface area and weight unreasonably increases the risk of injury to the patient and is a less safe design."

Did I read that correctly?

A. Yes.

Q. And my question is when you say that this mesh design unreasonably increases the risk of injury, compared to what?

A. To a material -- that is, in fact, the most important thing, you have to do it in comparison. If you compare the 108 grams of the Prolene® mesh with the 42 grams of Gynemesh® for the 34 grams of ULTRAPRO™, it has a surplus, it has more material, it has more surface. So if you compare these two, you have more contact area to the tissue and, therefore, you will have intensified tissue reaction.

So if there is no need to have this amount of material, if you can reduce it, if you can produce, if there are some facts that allow you to reduce the amount of material of the Prolene® mesh by half, then you will have an improved tissue reaction and, therefore, you will lessen the scar formation, you will lessen the risks for the patient. That is it. Prolene® mesh is at the maximum. In comparison to all other meshes, it's the maximum of the weight of the

material that is placed in this area and, therefore, it is, of course, it is heavy-weight. I think it's the heaviest monofilament mesh that I know, and if you can reduce the amount of material, that has been the sense of our work, then you improve the tissue reaction and reduce the risk.

Q. Didn't we decide yesterday that weight was not the determining factor in the intensity of the foreign body reaction?

MR. ANDERSON: Objection to form.

Go ahead.

THE WITNESS: In fact, that is -- yeah. If you have a Prolene® with these fibers and just reduce the amount of material, using a similar fiber, the same fiber, but just reduce the amount of material, of course, you will increase the pore sizes, you will reduce the material and you will improve the tissue reaction.

If you just stick to the weight and change the fiber from 120 microns

to 2 microns and create a multifilament made of polypropylene, then you are right, completely right. That is -- but this has been a -- an important part of our discussions because we, that is coming from Aachen, that is -- has been our work to stick on the importance of the pores and not of the weight.

So but sometimes it is more easy to reduce it to this to make it better understandable for the people.

Q. Doctor, do you have any clinical data to which you can point to support your opinion that the Prolene® mesh increases the risk of injury in the treatment of stress urinary incontinence above other materials for the same application?

MR. ANDERSON: Objection.

THE WITNESS: As I pointed out yesterday, the clinical data unfortunately that are provided, they are too limited to allow this consequence; however, the basic

principle that heavy-weight, a huge amount of material locally, small pore size, that this is linked to an increased risk, there are several studies showing it and not least because of this in the guidelines, in the meta-analysis for surgical meshes for hernia repair they're usually already is a statement that you have to consider light-weight and large pore.

QUESTIONS BY MR. THOMAS:

Q. You referred to a meta-analysis for surgical meshes for hernia repair.

Have you considered the meta-analysis for the use of meshes for stress urinary incontinence?

A. We mentioned yesterday I'm deeply aware about the fact that the limited value of meta-analysis.

Q. Okay.

A. It just -- it is helpful to confirm the importance of weight and pore size. In general, that this is -- that has a

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strong impact of the clinical results. There is no doubt about it. But as I pointed out yesterday, it is impossible to see or to prove any inferiority or superiority of any specific device.

Q. Also in your answer, you referenced several studies showing this basic principle.

Are these all animal studies?

A. No, there is -- if you are -- if you're trying to figure out what is the relevance of this mesh material discussion in the field of hernia surgery, and the field of hernia surgery is a little bit older than this for the pelvic floor and a lot of -- and we introduced the meshes, I think, earlier, if you try to figure out what is the relevance there, then you find there are several meta-analysis meanwhile summarizing clinical studies, and there are guidelines for the clinical treatment based on these clinical trials and giving the recommendation to use large pore material, reduce light-weight meshes in the treatment -- for

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the treatment of hernia patients.

So that confirms that the principle to think or to consider the mesh material and the weight and the pore size, that is well-accepted in the hernia society, yes.

Q. Is it fair to understand, Doctor, that you're relying upon your training, education and experience in connection with the care and treatment of hernias to support your position that mesh used in the treatment of stress urinary incontinence has the same risks as the mesh that's used in hernia repair?

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: Of course, my knowledge of the Prolene® is based on our preclinical studies that we did in the animal models, from our clinical experience, from the experience we have got from hernia patients. Overall, everything confirmed that the tissue response is quite similar.

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That there are some similarities when you place meshes in living tissue, that you have some similarities. There are -- depending on the specific location, there can be some differences in the tissue reaction, but there are very important aspects that are quite similar that a mesh behaves similarly in the various areas from the point of the histological analysis.

There are considerable differences in the biomechanics and there we know that pelvic floor has different biomechanics. We have a similar area in the reenforcement of the diagram where we have some forces as well. So the biomechanical problem makes it as a functional difference to the hernia mesh. That is even more in another respect when you're taking a hernia mesh to use it in another functional condition. It's a concern and problem.

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QUESTIONS BY MR. THOMAS:

Q. Let me try my question again and maybe you didn't understand it.

What I'm trying to understand, we were talking about clinical studies used to analyze the extent to which mesh causes problems in the pelvic floor -- strike that.

The goal of my question was to try to determine whether there are clinical studies on which you rely to analyze the problems of complications with the use of mesh for the treatment of stress urinary incontinence, and I think you told me that you rely on your clinical experience in hernia for that information.

Is that true?

MR. ANDERSON: Objection to the form of the whole question.

Go ahead.

THE WITNESS: No, that is, of course, not true because to my opinions, it is -- it is necessary to see whether there are some complications when using it as a

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sling, and as you know from the documents, there are some specific complications which are different from those from hernia surgery. So you have to look to the specific literature what may be some consequences.

However, the general opinion whether it's heavy-weight, whether it's a higher risk than another, you have to take all of this information together.

QUESTIONS BY MR. THOMAS:

Q. Okay. Is it your testimony that you need to go to the specific literature to learn what may be the consequences of the use of mesh for the treatment of stress urinary incontinence?

A. You have to consider this as well. You have to include it into this.

Q. What literature have you considered to understand the complications which arise from the use of mesh in the treatment of stress urinary incontinence?

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A. I'm not able to give you a list of all of the documents I've downloaded during the past years. I regularly are looking to the literature, and I know it's hundreds of documents every week are coming, some new. So, yeah, several. I looked at several of them.

Q. Can you tell me one?

A. One of these publications?

Q. Yes, just one.

A. Sling. As I told you, it's the NICE meta-analysis.

Q. Okay.

A. That their -- it is -- as I told you, the AWMF, it is study for PVDF meshes from Norway that has been published this year. There has been several studies comparing the textile properties.

Q. Are there any clinical studies about which you're aware that suggest that the design of the Prolene® mesh increases the risk of injury to a patient over a larger pore, lighter-weight mesh?

MR. ANDERSON: Objection again.

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Asked and answered.

Go ahead.

THE WITNESS: I did not know that there has been a comparison of different materials as it has been done in the hernia -- in the field of hernia surgery where we make randomized controlled trials comparing light-weight and large pore meshes. I don't know whether -- I don't know in the moment a study where someone compared two different slings with the outcome. But as we discussed yesterday, clinical studies are very limited in clarifying whether one material really is better than the other. It is very likely that if you make such a study that you get nonsignificant results due to the variation in your collectives.

QUESTIONS BY MR. THOMAS:

Q. Is it true, simple question, that there are no -- it's true that there are no clinical studies about which you're aware

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that suggest that the design of the Prolene® mesh increases the risk of injury to a patient over -- in the treatment of stress urinary incontinence over a larger pore, lighter-weight mesh; is that true?

MR. ANDERSON: Objection. Asked and answered again.

THE WITNESS: It isn't true because you didn't reduce it to the pelvic floor. So if you made it in general --

QUESTIONS BY MR. THOMAS:

Q. Oh, I think I did.

A. You just asked me if I'm correct. If there are clinical studies showing that Prolene® has more complications in comparison to heavy-weight or I missed it. So a general, there are clinical studies. For the use as sling, I don't know any.

Q. Okay. So just to make sure we're clear. For the use of slings, mesh slings, in the treatment of stress urinary incontinence, you're unaware of any clinical studies that show that the use of Prolene®

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mesh increases the risk of injury to a patient in the treatment of stress urinary incontinence over a larger pore, lighter-weight mesh; is that true?

MR. ANDERSON: Objection. Asked and answered.

THE WITNESS: That is true.

QUESTIONS BY MR. THOMAS:

Q. Okay. Doctor, on page 2 of your report, you continue and say, "The Prolene® mesh in TVT® is a small pore mesh."

How big is the pore in TVT® used for the treatment of stress urinary incontinence?

A. This is -- this is a question that is -- that has to be explained in detail from various aspects. It is insufficient to just make a measure in one dimension and say this is a pore.

In the '90s, we made with the VYPRO mesh with 3, 4, 5 millimeters of pores roughly when you make these measurements. So these are considered really as large pores. There are others that are from the

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microscopical view can be regarded as small pores. So to make a precise measurement of the pore size or the distribution of the pores, it was a problem for a long time.

We first started in 2000, I think, for the first time that we tried to figure out that it is a distribution, that every mesh has some smaller pores, some larger pores. So one specific value -- yeah, figure and value of a pore, this does not reflect the reality of a mesh construction. So you have these different pore sizes in every mesh.

And then we got aware that if you look to the histology and not to the foreign body reaction around the filaments but to the pores inside, then you see the differences that in the VYPRO and the ULTRAPRO™, you don't have this bridging and there are, if the filaments are coming closer together, then you have these pores filled by scar tissue. So there seems to be a difference.

In 2003, 2004, we started to

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get objective analysis of this pore distribution. To make it easier to understand what was found in histology, to make it easier to understand what are the consequences if you change something of the textile construction, what is the consequence to the pore sizes and the distribution of the pores, therefore, we made this machine or we developed this machine together with Professor Mühl and it was able to get clear images of a mesh construction and if you are using the textile porosity as before, you get this distribution.

The next decision has to be how to compare distributions to define which is better than the other. And it is statistically, scientifically it is not easy to make a reliable comparison of distributions and, therefore, we decided to make a cutoff, to define a cutoff because we have seen at various histological sections that there may be a minimum pore size that is increasing the risk for this bridging. It has been with the Marlex. It has been done

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for the first time with the Marlex, and we have -- somewhere in your documents there is a PowerPoint slide with a distribution and then there is on the left side, there is a distribution for the Marlex and there we marked in between 600 and 800 microns that we saw and we measured the distance of the filaments that we saw that below this border of 600, 800 with the Marlex and you have this bridging.

Later on, 2003, 2002, we took as a limit -- as a cutoff to separate the meshes with low risk and high risk by 1 millimeter because we then had the values of the experiments that has been published by Conze where we measured it in Aachen.

But at the beginning, we noticed that there is an impact of the polymer so we separated for PVDF and PP. Of course, there are a lot of other impact factors that can do it.

So the question what is small or what is the best pore or what is the pore cannot be answered by giving you just a

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figure. If you take the extremes, the ULTRAPRO™, the VYPRO, was a pore of 3 to 5-millimeter. If you made a linear measurement there with all of the limitations, all restrictions, please don't stick me to this number 3 to 5-millimeter. It's just a shortening of this. This is low risk for bridging, and whereas, very small pores has a high risk of bridging. That is the message.

Q. Doctor, have you ever attempted to physically measure the pore in the Prolene® mesh used in TVT® for stress urinary incontinence repair?

A. Whether we made a measurement of the Prolene® mesh?

Q. Yes.

A. Dr. Mühl did it.

(Klinge Exhibit 20 marked for identification.)

QUESTIONS BY MR. THOMAS:

Q. And I'm not -- and just for the record, what you're talking about is Exhibit Number 20, the article that you coauthored

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with Dr. Mühl in 2007, "The New Objective Measurements to Characterize the Porosity of Textile Implants."

Is that correct?

A. Yes.

Q. My question is in the 1990s when you're doing your experiments, did you ever measure the pore size of the TVT® mesh used -- strike that.

In the 1990s when you were studying first generation Prolene® mesh, which you call old Prolene®, did you ever measure the pore sizes?

A. The pore sizes in the '90s have been done first by just making linear measurements. We know -- we all know that this is not accurate to give a good reflection of the pore size, but at that time, it was the way we did it, and the next thing we tried to do is the textile porosity. So it is impossible. It is still today impossible to measure a pore size.

Q. Okay. Still today impossible to measure a pore size, correct?

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A. It depends from your definition what you're thinking of as a pore size. What is -- of course, you can make images of the pore area so -- first of all, you have to define what is your meaning of pore size, in what context you want to have this. General finding.

Q. Doctor, are you -- I am sorry, I didn't mean to interrupt you.

A. Yeah.

Q. Doctor, are you aware of any standard that tells you or Ethicon how to measure pore size?

A. I think -- or the -- the best solution to get an idea or to try -- an objective measurement to make a characterization of textile structures by the use of pores, this is done in this publication.

Q. Okay. Other than the Mühl publication, Exhibit Number 20 that we've talked about before, are you aware of any standard promulgated by any regulatory, public health authority or company that tells

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you or Ethicon how to measure its pore size?

A. I know there are some -- there has been some publications related to the textile porosity. How to make the textile porosity in a two-dimensional way. There are some -- there are maybe some experimental other attempts to grasp the problem of pores to describe this. But there is, of course, I don't know any official standard showing you have to do it like this.

Q. In the '90s when you were doing your own studies, you measured them in a linear fashion; is that true?

A. At the beginning, yes.

Q. Okay. And tell me how you did that. What points in the pore did you measure?

A. As I remember, we had a visual impression what may be the mean distance in the pore. Not looking what is the farest distance, what is the shortest, but what may be the mean roughly.

But, again, the purpose at that time was to give a hint to the reader, to

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show the difference between 3 millimeters and .3 millimeters. And, therefore, this gives a good impression that the textile construction was different.

Q. Before VYPRO, was there anything in the literature about light-weight -- strike that.

Before VYPRO, was there anything about a comparison of large pore to small pore in the literature?

A. I'm not aware of it, no.

Q. Before VYPRO, was Prolene® known as a large pore mesh?

A. These words were not -- it was not a discussion. At the beginning of the '90s, you already had the Mersilene. Mersilene is a mesh with a very low weight. You had the Prolene® with very high weight, and there hasn't been any discussion about the different textile characteristics. I think that is what we introduced. If you look to the literature what has been published until '99 with the search for meshes, you will hardly find any good data up

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to there. It's a dozen experimental studies until this and then it's going up.

Q. Was the first generation 6-mil Prolene® mesh used for hernia repair, which you refer to as old Prolene®, ever described in the literature as large pore macroporous mesh?

A. In what -- before 1995, that has not been the wording for -- to describe a experimental setting there. Yeah, later on, I know that there is some of the documents where we took over -- I think ourselves took over some measurements provided by the manufacturer and said -- or took it in and mentioned it as 1.2 millimeter, the pore size.

So, but, yeah, as we discussed already, it is not sufficient to give a real impression of pore. It's too difficult.

Q. Doctor, we spent a lot of time yesterday talking about the progress in your understanding about the design of meshes beginning in the party in Christmas in 1993?

A. Uh-huh.

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Q. At any time in your research from 1993 to the present, in your experience, was it ever appropriate to describe Prolene® as a large pore macroporous mesh?

A. It is in contrast. If you're looking to our experimental publications, there we took the Prolene® mesh in our experiments as a control for a mesh that is usually bridging, that induces usually an intense inflammatory and fibrotic reaction. That was our control for many of these experiments.

And on the other end, we really had some large pores, light-weight mesh materials, but the prototype of a heavy-weight, small pore meshes, that has been Marlex and Prolene®.

Q. My question, Doctor, is a very simple one and I'm trying to understand whether based on your 20 years of experience in this field, at any time during that 20 years whether the state of knowledge about mesh design was such that it was appropriate to describe first generation 6-mil Prolene®

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mesh as large pore and macroporous?

MR. ANDERSON: Objection to form.

THE WITNESS: No. No. It is --

QUESTIONS BY MR. THOMAS:

Q. You're familiar with the Amid classification?

A. Uh-huh.

Q. Is that "yes"?

A. Yes. Yes. Sorry.

Q. And you know under the Amid classification that Prolene® is a Class I mesh? Is that "yes"?

A. Yes, I know it, but I have to explain this is not fair because now we are switching to different definitions of large pore.

Q. Okay.

A. I --

Q. Can I --

A. From our work, it is very clear what large pore is. That is a large pore. The consequence of a large pore that you have

a low risk for bridging. That is the message of all our work, and this shouldn't be put together with the definition of large pore in the Amid classification because he has a different aim and purpose to do so.

So it is mixing up two different things and it is increasing the confusion that everywhere happens.

Q. You've talked about the Amid classification at length in other depositions and I'm not going to explore that again, but feel free --

A. Me neither.

(Klinge Exhibit 21 marked for identification.)

QUESTIONS BY MR. THOMAS:

Q. Doctor, I've handed you what's been marked as Exhibit 21.

Exhibit 21 is a --

MR. ANDERSON: Excuse me, Counsel, can you tell me what the F mesh is? Mine is cut off.

MR. THOMAS: Yeah, mine is too. I was just going to say that for the

record, but I can't, but I'll get them for you.

QUESTIONS BY MR. THOMAS:

Q. Exhibit 21 a journal article in the International Urogynecology Journal, volume 19, number 5, May 2008, it's titled "Tensile Properties of Five Commonly Used Midurethral Slings Relative to the TVT®."

You cited this article in your paper, haven't you? Do you remember that?

A. Cited in what --

Q. In your report?

A. Yes. Yes. It's very nice, very interesting study.

Q. And this study compares the tensile properties of five different slings against the Johnson & Johnson TVT® sling, correct?

A. The textile properties, yeah.

Q. Okay. I want you to turn to page 657 of Exhibit 21, to Table 1.

And Table 1 shows, "The textile properties (including loaded failure) provided by the manufacturers listed at the

top (AMS, American Medical Systems) describing the different meshes tested in this study.

Have you looked at this table before?

A. Yes.

Q. And there are six different types of meshes that are used for the treatment of stress urinary incontinence; is that correct?

A. That is correct.

Q. And the authors in the Moalli paper have a category for mesh thickness, correct?

A. Yes.

Q. And mesh thickness is exactly what it says, it's just how thick the mesh is?

A. Yes.

Q. Then it has pore size and it shows the pore sizes for each of these meshes used for the treatment of TVT®, and you understand that Gynecare is the TVT® mesh, correct?

A. Yes.

Q. And the Gynecare mesh is shown as having a pore size of 1,379 microns, correct?

A. It is written here, but we pointed out, I think, very extensively that the number of 1,379 microns is a measurement within the textile mesh, but it does not reflect the textile characteristic in regard to pores and porosity because you always have a distribution.

But you see still here in the year 2008, it was still used there, but this is not what is the relevant information to predict the tissue reaction there.

Q. Do you view --

A. So it's not relevant. It's not really relevant.

Q. Okay. Is it inappropriate from a scientific perspective for the authors in the Moalli study, Exhibit 21, to regard pore size in this fashion?

A. No, it is -- no. It is -- a lot of people is doing it when they don't --

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when they were not aware of the problems of this. You cannot discuss every parameter in detail in every manuscript, otherwise, you -- so every manuscript is a comprise. You can present some data.

But in this litigation, we're sitting here and discussing about the pores of the Prolene® and when you cited this document as proof that Prolene® is a mesh with pore size of more than 1,000 microns, that is -- that is not relevant. It is a -- it is a paper, it is a manuscript and they did the best to take the information they got there, but it doesn't help me for my opinion whether it's a small pore or large pore. That is the fact that has to be clear, I think.

Q. I understand that. I actually am going to use this for a whole different reason than you think.

A. I'm not sure.

Q. I know that, but that's why I get to ask the questions.

A. And I have to be concerned.

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Q. No, you don't.

So have you looked at the mesh of Boston Scientific used in the treatment of stress urinary incontinence?

MR. ANDERSON: It's a specific question. Have you looked at the mesh of Boston Scientific?

THE WITNESS: No.

QUESTIONS BY MR. THOMAS:

Q. Have you looked at the mesh manufactured by AMS for the treatment of stress urinary incontinence?

A. No.

Q. Have you looked at the mesh manufactured by BARD for the treatment of stress urinary incontinence?

A. No.

Q. Have you looked at the mesh manufactured by Caldera for the treatment of stress urinary incontinence?

A. No.

Q. Have you looked at the mesh manufactured by Mentor for the treatment of stress urinary incontinence?

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A. No.

Q. Are you aware of any other mesh marketed in the United States for the treatment of stress urinary incontinence other than the ones listed in Exhibit 21?

A. Aware in the meaning that I know that there are several others. I'm not -- I'm not able to present the total list of all possible sling materials there.

Q. Okay. The PVDF mesh for the treatment of stress urinary incontinence is not available in the United States.

You agree with that?

A. To my knowledge, it is correct.

Q. And the PVDF mesh from FEG that's used for the treatment of stress urinary incontinence has not been approved by the United States Food and Drug Administration.

Do you agree with that?

A. It is -- yeah, to my knowledge, it is the fact. But I'm not sure whether they really sent it to them to have it checked.

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Q. I understand.

A. Or whether they didn't do it.

Q. I don't know whether they've asked either, but --

A. But this is -- I think this is a major difference.

Q. Okay. Would you agree with me that the pore size for the Gynecare mesh used for the treatment of stress urinary incontinence, the Ethicon TVT®, has a pore size that's larger than the other five that are listed in the Moalli study?

A. No.

Q. Why?

A. Because the question what is the pore size, whether it's bigger than the other, it cannot be answered. You have this distribution. You have some pores bigger than the others. You have to make the testing or you have to figure out what is the specific distribution of the various pore size and then when you want to make a cutoff, when you include a cutoff, then you have to look to the effective porosity and then you

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can get an opinion whether one is better than the other.

Q. Okay. Have you ever analyzed the extent to which meshes available in the United States have an area of pore size that are larger than the Ethicon TVT® mesh, any of them?

A. Though even the information about the area has some limitations, but I have to say, no, I never made systemic analysis of the competitor -- of the slings from the competitors to have a systemic analysis of the other devices.

Q. It's your opinion that the Ethicon TVT® mesh used for the treatment of stress urinary incontinence does not have sufficient effective porosity as measured by, I think it's Exhibit Number 20, the Mühl study, to be used safely in a woman for the treatment of stress urinary incontinence; is that true?

A. The idea was or the facts are that when you look to the histology, reaction to this mesh material, you always hardly ever

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or always -- almost always find some bridging when looking to tissue around the Prolene® mesh. Therefore, it behaves biologically as a small pore meshes. Then if you -- and this is consistent to the measurements and this is consistent to the missing effective porosity in the Mühl testing.

So this is very, very consistent. If you look to the competitors, it is hardly difficult to find -- just to see the differences from the images between the various devices. So I think -- I assume that we will get similar results.

MR. ANDERSON: And you were pointing to page 658 of Exhibit 21 when you said "images"?

THE WITNESS: Yes. Figure 2 and --

QUESTIONS BY MR. THOMAS:

Q. Let me break down your answer a little bit.

When you measure pore size, it's your expert opinion that it's appropriate to use the effective porosity

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analysis that you and Dr. Mühl devised in Exhibit Number 20, correct?

A. Please can you rephrase the -- I didn't -- I'm not sure whether I got the first relationship in your sentence.

Q. When you measure pore size, it's your expert opinion that it's appropriate to use the effective porosity analysis that you and Dr. Mühl devised in Exhibit Number 20, correct?

A. I can say that the effective porosity that we mirrored from the study from Professor Mühl, they give some relevant, important information about the pores, the distribution of the pores in the Prolene® mesh. So, therefore, this is consistent with the histological findings and, therefore, my opinion is based or includes this one.

But it wouldn't be correct to reduce every statement about pores to the effective porosity.

Q. But isn't it true for purposes of your analysis of the extent to which a mesh is designed inappropriately insofar as

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there's adequate pore size for appropriate tissue integration that you rely on the study that you and Professor Mühl prepared, Exhibit Number 20, to determine the appropriate porosity measurement?

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: It's a very long sentence, but I try to answer it however.

You have to understand that the measurement of Professor Mühl helps us to understand and to predict the tissue response.

If you assume the textile engineers from Ethicon would change the machine a little bit and the Prolene® really is a challenge for this machine. If they changed the machine a little bit and made the pores a little bit wider, then probably you get with the testing of the machine an effective porosity of maybe 40 percent, yeah.

In this case that the machine would have been changed a little bit, then we would have problems because in the histological analysis we saw the scar formation, we saw this bridging and, therefore, it is one way -- it is one important information, the effective porosity, and it helps to explain why certain devices have some problem.

And we would have serious problems if there is a mesh device, and I don't know whether the competitors have it, which may be 1.1 millimeter. So that you have an effective porosity, then the consequence for us would have to be to rise this limit. But in the moment, we feel consistent and satisfied with this limit.

QUESTIONS BY MR. THOMAS:

Q. Under the Mühl study that you and Professor Mühl did in 2007, Exhibit Number 20, is it fair to understand that

meshes with an effective porosity with less than 1,000 microns as measured by Professor Mühl, you believe present an increased risk of injury to patients?

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: Yes.

QUESTIONS BY MR. THOMAS:

Q. And that meshes with an effective porosity of greater than a thousand microns -- strike that. Let me start over again.

Do you know whether any of the meshes on page 657 of Exhibit 21 have an effective porosity of greater than 1,000 microns as described in Exhibit 20?

A. No, I don't know.

Q. As you look at the relative pore sizes as measured by Moalli and others where you see that the Gynecare mesh has a pore size measured at 1379, all of the other manufacturers mesh sizes as measured by Moalli are lower, correct?

MR. ANDERSON: Objection.

Go ahead.

THE WITNESS: Is it possible not to make a comment to this?

MR. ANDERSON: No, you have to answer the question, but you can --

THE WITNESS: I think it is inaccurate to compare textiles, different textile constructions by the use of these values for the pore size. It is inaccurate and insufficient.

QUESTIONS BY MR. THOMAS:

Q. Let me ask you this question, Doctor.

Do you know whether any mesh used for the treatment of stress urinary incontinence available in the United States has an effective porosity of greater than a thousand microns as measured by the Mühl study, Exhibit 20?

A. No, I don't know.

MR. THOMAS: Let's take a break, please.

MR. ANDERSON: Okay.

(Off the record at 9:46 a.m.)

QUESTIONS BY MR. THOMAS:

Q. Doctor, did you have any involvement in the development of the 5-mil hernia mesh used by -- marketed by Ethicon for pelvic -- strike that.

Doctor, did you have any involvement in the development of the 5-mil hernia mesh marketed by Ethicon?

A. No, I don't have.

Q. Do you know whether the 5-mil hernia mesh marketed by Ethicon is still used today for the care and treatment of hernias?

A. No, I don't.

Q. Do you know whether the 5-mil hernia mesh made by Ethicon is appropriate for use in the treatment of any hernias?

A. For any hernias in the way that there may be some hernias that should be -- can be treated with this, yes.

Q. And under what circumstances would it be appropriate to use a 5-mil Ethicon hernia mesh?

A. If this is a -- in its textile properties comparable to what we know as the

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Prolene® mesh. If there aren't any severe differences because I'm not familiar with this mesh and its textile characteristics. It should be considered as a heavy-weight, small pore, very stable mesh material and the indication for these mesh materials in general from my point it's more or less the replacement of defect and not the use for the treatment of a hernia.

Q. When you say it's for the "replacement of a defect," what do you mean?

A. There are some cases where you have a complex defect of all tissues. There are various layers of tissues. In a hernia, you mainly have a hole and you have some stable surrounded tissue there and, therefore, the principle for the treatment of a hernia is to cover the hole with a wide overlap.

If you don't have this strong tissue that can cover the mesh, then it is necessary to have a more stable mesh with a restricted stretchability, otherwise you have a bulging here. And I think still the best

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indication for using these meshes are when you made a resection of the thoracic wall here in this field and when you want to make a repair in this area.

If you remove the ribs, then you need some very strong material without any significant flexibility.

Q. So would it be appropriate for a hernia surgeon in certain indications to use 5-mil hernia mesh for the repair of a hernia defect?

MR. ANDERSON: Objection. Asked and answered.

Answer it again.

THE WITNESS: There will be some specific indications where you have -- where the surgeon can have some good arguments to use this material, yeah.

QUESTIONS BY MR. THOMAS:

Q. Is Marlex mesh still an acceptable option for a hernia surgeon to use in the treatment of hernia patients?

A. You have to define what is

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acceptable. Acceptable in a legal way, yes, so all of these mesh materials that are permitted to be used in surgery can be used without any legal consequences.

If you're thinking of the possible risks for your patients, then it has to be seen in relation to the patient and the specific conditions and the specific hernia type whether you use a Marlex mesh, yes or not. There is no principle answer to this question.

Q. Based on your training, education and experience in mesh research and your experience as a hernia surgeon, would you ever use Marlex mesh in any of your patients?

A. As I told you, it is -- the basic question wouldn't be whether to use specifically Marlex or -- yeah, but the question would be whether to take a heavy-weight, stable, small pore, whatever you want to -- whatever you prefer to name these type of meshes. Whether you want to take these more stable meshes or whether you

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can reduce the amount of material to come to a satisfying result for the patient. That is the decision you have to do, and I can imagine that there are some conditions where Marlex is an appropriate -- Marlex or Prolene® or something like this is an appropriate selection.

Q. You've described one circumstance where you thought it might be appropriate to use a 5-mil Prolene® mesh for a repair.

Are there others that you can think of?

A. Maybe replacement in the brain, but I -- I don't -- or I do not have any specific condition in the moment where I think that it is necessary to use a mesh like Prolene® or Marlex.

Q. Over this litigation, I've heard a number of different estimates of the hernia surgeries conducted around the world in a year.

What is your current best judgment about how many hernia surgeries are

conducted around the world each year? Using mesh, I am sorry.

A. I never counted it, but I've read this publication from Sanders and Kingsnorth. They estimate the use of meshes with about 20 million per year. I know that there are in the US about 1 million hernia operations a year. In Germany, it's about 300,000 hernia operations in the year. I guess India and China will contribute significantly, however, I don't know the figures.

Q. Do you have any information that allows you to estimate of the 300,000 hernia surgeries in Germany using mesh, how many use Prolene® 5-mil mesh?

A. For the treatment of groin hernia, I don't know any. For the treatment of incisional hernia, there will be some few that are still using heavy-weight meshes.

Q. And of the 300,000 hernias in Germany, do you have a breakdown into groin and incisional hernias?

A. Incisional hernia it's about

30,000 to 50,000. And there is a -- maybe about 50, 60,000 infant hernias that are treated without any mesh.

Q. Of the 30 to 50,000 incisional hernias, which is I think the only category where you said it would be appropriate to use Prolene® 5-mil hernia mesh, what percentage of those incisional hernias would be treated with 5-mil hernia mesh?

MR. ANDERSON: Objection to form. Misstates -- mischaracterizes testimony.

Go ahead.

THE WITNESS: I do not have the -- I do not know the market shares. I know that the predominantly used mesh in Germany is the ULTRAPRO™. It is a large pore, small pore meshes in the groin and for incisional hernia, and I cannot remember in the past years anyone reporting about his experience with a heavy-weight, small pores, either Marlex or Prolene®.

QUESTIONS BY MR. THOMAS:

Q. Do you include any other mesh, specific mesh brand names that are currently used when you describe the Prolene® 5-mil and the Marlex as a heavy-weight, small pore mesh, any other meshes on the market?

A. There are other manufacturers as Covidien and Brown. In Germany, there are, yeah, other manufacturers as well. So there are lots of -- finally Coda comes up with a list of 200 different mesh materials.

MR. ANDERSON: I'm not sure he understood your question. He was asking about how many other manufacturers make heavy-weight, small pore meshes.

Did you understand that?

THE WITNESS: Well, there are other -- yeah, there are some others from Brown, others from Covidien, others from AraVista.

QUESTIONS BY MR. THOMAS:

Q. Within your category that you've described as heavy-weight, small pore

mesh, including as you describe it Marlex, the Prolene® 5-mil, do you know what percentage of the incisional hernia repairs use the heavy-weight, small pore meshes?

A. I don't have exact data. So far I have heard that market share of ULTRAPRO™ was about 70 percent in Germany.

Q. Does that mean --

A. So that will be the most easiest way to figure out what is the relationship between Prolene® and ULTRAPRO™ in Germany.

Q. Is it just as simple to say that the remaining 30 percent is a heavy-weight, small pore mesh?

A. No, all of these other manufacturers have light-weight, there's tie mesh, light-weight, material reduced. There's something midway. Again, we're coming into this confusion about the weight material.

Q. Okay.

A. The conclusion that everything else is heavy-weight is not true.

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Q. Okay. That helps me.
But what I'm trying to figure out, and maybe you don't know the answer to this, do you have any information that leads you to be able to estimate the percentage of heavy-weight, small pore meshes used for the treatment of incisional hernias?
A. Apart from this estimate, no.
Q. Okay. This estimate, I don't think you gave me an estimate.
A. Estimate is 70 percent market share of the ULTRAPRO™.
Q. Okay.
A. So at least it should be 70 percent.
Q. Okay. Doctor, on page 43 of your report, which is Exhibit 11, you begin your discussion of fraying/particle loss/MCM/LCM/curling/roping.
Do you have that?
A. I have it, yes, I see it.
Q. In 2012 when your deposition was taken, I believe your testimony at that time was that you didn't have any information

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that fraying, particle loss from mesh insofar as it related to pelvic organ prolapse created any injury of clinical significance.
MR. ANDERSON: Is that a question?
MR. THOMAS: Yes.
MR. ANDERSON: It doesn't seem like one. I'll object to mischaracterizing testimony.
QUESTIONS BY MR. THOMAS:
Q. Let me start over again.
As you sit here today, Doctor, are you aware of any literature that supports the contention that any fraying of TVT® mesh leads to clinically significant results in patients who receive the mesh for the treatment of stress urinary incontinence?
A. There is good evidence that fraying, increase of surface induces an inferior tissue response, but I don't know any clinical study testing the relationship between particle loss and the clinical outcome, and I cannot imagine that it can be done in a clinical study.

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Q. Is the same thing true for each of these categories that you have in heading G on page 43 of Exhibit 11, do you have any clinical data to link what you understand to be these conditions being fraying, particle loss, machine-cut mesh, laser-cut mesh, curling and roping, to any clinically significant conditions?
A. No, unfortunately, I did not find any study dealing with these problems.
Q. Doctor, the next several pages in the description of the fraying, particle loss section beginning on 43 of Exhibit 11, have you ever read any study that discusses risks associated with particle loss in vivo from Ethicon mesh used for the treatment of stress urinary incontinence?
A. I don't know any study that is testing the impact of this particle loss in an in vivo system.
Q. You were a hernia surgeon for how long?
A. I have been surgeon starting in 1985, and I'm still surgeon. I have been

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operating hernias from 1985 to 2006.
Q. Okay.
A. I'm not a hernia surgeon because in Germany you don't have hernia surgeons.
Q. I see.
Have you had any surgery -- have you done any surgeries since December 2006?
A. No. Not in humans.
Q. Do you still have your license to practice surgery if you like?
A. Yes.
Q. When you used mesh for the treatment of hernias, did you on occasion have to cut the mesh?
A. Usually you have to trim it, yes.
Q. And how do you trim it?
A. Outside of the OR field with specific other gloves to reduce the risk for contamination there, then you get some sterile scissors and you're cutting out of the OR because when you're trimming a mesh,

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always you have some sort of particle loss, always. There are some structures that create more. It depends on the bindings, it depends on the coarse of the filaments. So we know that there is some particle loss when you trim this mesh and, therefore, we did it outside and then we took the trimmed mesh and took these mesh and placed it in the groin or in the abdominal wall. So we try to avoid to trim it when it's already placed in the tissues.

Q. And is it fair to understand that for the approximately 20 million hernia surgeries conducted a year using mesh that you would expect those hernia surgeries to involve the trimming of the mesh in some way?

A. Yes.

Q. Do you expect based on your training, education and experience to the extent there was a clinical problem associated with particles being shed by mesh in vivo during the surgery that it would be reported in the literature now?

A. No. No. I don't think that

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the -- that it has -- that there has -- would have to -- or that there should be a report about this and I don't think that the absence of such a report indicates that it's not a problem.

Q. In the 20 years of mesh research that you've conducted, have you ever studied the clinical effects of particle loss from mesh?

A. We only studied in these years the impact of surface to bacteria adherence, to tissue response, cellular response. So increased surface means enhancement of this reaction. We never made a specific investigation whether reduction of particle loss by 10 percent leads to a change of this. We never did it.

Q. Did you ever consider analyzing the extent that particles shed by hernia mesh create any risk of injury in patients?

A. As I told you, we are convinced or we know that increase of surface will mean increase of tissue response and that means finally increase of scar and increase of the

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risks. In hernia surgery if you place a mesh 20 to 30 centimeters in a flat area and you made this trimming of some corners there in relation to the abdominal, surgical trauma, in relation to the mesh area, it is a considerably small area where there may be some effect.

We never selected a mesh material by thinking or asking for the amount of particle loss or, yeah, selected the mesh material with the least amount of particle loss. In hernia surgery, it was not an issue and I don't know anyone who is doing so.

Q. Prior to this litigation, in the 20 years of experience that you had in mesh research, did you ever identify a potential risk of injury to a patient associated with particles that are lost from a mesh during hernia implantation?

A. Only in the sense increased surface generally increases the risks but not specifically that we had some patient with a specific complication that can be related to particle loss, no.

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MR. THOMAS: I am sorry, I have to take a quick break again.

MR. ANDERSON: Okay.

(Off the record at 10:21 a.m.)

QUESTIONS BY MR. THOMAS:

Q. Doctor, as a part of your opinions in this case, have you analyzed the extent to which you think that the Ethicon mesh used for the treatment of stress urinary incontinence sheds particles in vivo?

A. Can you please repeat the first word?

Q. As a part of your opinions in this case --

A. Yeah.

Q. -- have you analyzed the extent to which the Ethicon mesh used for the treatment of stress urinary incontinence sheds particles in vivo?

A. Sorry, whether we analyze it or whether --

Q. Yes.

A. We did made a systemic analysis, but I saw in one of the specimen

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that I was sent, that I got of the explants there are at least one area where you can be sure that this is a particle that has been there since the implantation.

There are a lot of other particles there, but you cannot be sure whether it's by dissecting for the histological preparation, but at least there is one and I made an image where this one particle can be seen there.

Q. We'll talk about that a lot later.

My question is -- I think you've already answered.

You've not made any systemic analysis to measure the extent to which the Ethicon mesh used in the treatment of stress urinary incontinence sheds particles in vivo; is that fair?

A. No quantitative analysis.

Q. Have you ever -- strike that.

Did you compare the extent to which Ethicon mesh used for the treatment of stress urinary incontinence compares to

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hernia mesh to determine the extent to which one sheds particles in vivo compared to the other?

A. Compared to hernia mesh?

Q. Yes.

A. I didn't get it.

Q. Have you made any kind of analysis to understand whether more particles are shed when you trim hernia mesh and implant it for hernia repair as compared to the placement of Ethicon mesh for the treatment of stress urinary incontinence?

A. First of all, it is similar mesh. It is mainly similar textile structures so when you cut these mesh structures, I wouldn't expect that there is any difference. The extent of trimming during the gynecological or urological operation, I don't know.

Q. Okay. Would you expect any particle loss between the placement of mesh in the treatment of stress urinary incontinence to be similar to the placement of mesh for the treatment of hernias?

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A. What I expect is that you cannot divide some particle loss when you're cutting a textile due to the way it is manufactured. Therefore, I expect that you will have some particle loss in both areas. The consequences and quantity -- and quantity may be different.

Q. Do you have an opinion as to in which area the particle loss is greater, whether it be hernia repair or stress urinary incontinence?

A. I think that -- or the particle loss depends on the textile structure of a specific device, whether there are some loose ends that can be released from the material, it depends from the lengths of the cutting, not from the amount of mesh material, but from the lengths of the cutting, the more trimming, the more particle loss you will have. The biological consequences, they have to be defined in relationship to the surgical trauma around.

Q. And my question is: Do you have an opinion to a reasonable degree of

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scientific or medical certainty that the hernia procedure has some degree of particle loss different from what you would expect from placement of mesh for the treatment of stress urinary incontinence?

A. My opinion is from what I've seen from all of the documents that the surgical trauma in hernia repair is much bigger than the application of a sling.

Q. And how does that inform your opinions about the amount of particle loss in either procedure?

A. As I told you, the amount of particle loss depends on the -- can vary between the different devices. It depends from the lengths of the trimming away.

Q. Okay. Doctor, do you know the extent to which a surgeon who implants Ethicon mesh, the TVT® classic, for the treatment of stress urinary incontinence trims the mesh?

A. I'm not an expert of how to handle this during the OR, but at least he cuts it.

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Q. And where does he cut it?
A. He cuts it to remove the needles beneath the skin level.
Q. Does he cut it intra-abdominally or outside?
A. He tear it and cutted it and then it slipped back, but you have to consider that you have a cutting of the mesh during the manufacturing process and, therefore, usually you have these particles there. We all know that there are some during the transport, during the preparation. There are some additional particles that is not necessary that they are released during the trimming process, but particle loss is a concern for textiles in general.
Q. For all meshes?
A. Overall. The amount will differ independent of the type of linkings and connections between the filaments.
Q. When a surgeon implants Ethicon TVT® mesh for the treatment of stress urinary incontinence, the only cutting of the mesh occurs after the mesh is placed, the needles

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are pulled through the skin and then the mesh is cut on the outside of the body; is that correct?
A. The trimming, yeah, outside.
Q. Okay. When the mesh is placed -- strike that.
When a surgeon places Ethicon mesh for the treatment of stress urinary incontinence, after the mesh is cut as you've just described, is the mesh secured to the tissue with anchors in any way, staples or sutures or anything of that kind?
A. No. No.
Q. Doctor, when a surgeon places Ethicon TVT® mesh for the treatment of stress urinary incontinence, what holds the mesh in place?
A. The mesh is kept in place because the surrounding tissue is filling or is -- yeah, is filling the pores of the mesh. So if you are using a sheet without any pores, it will be more easy to remove this. If you have a -- and this is a reason that we use textiles for the reenforcement of the

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tissues because we know that one place in the tissue it is -- it is more difficult to remove them again. Therefore, we had the similar discussions about fixation of meshes in hernia surgery.
Q. So when the surgeon places the mesh underneath the urethra for the treatment of stress urinary incontinence, it's the tissue of the patient filling the pores that keeps the mesh in place?
A. That is my belief, yeah.
Q. Now, do you have any understanding about how the mesh used for the treatment of stress urinary incontinence is placed?
A. I've seen a video.
Q. Okay. And --
A. Or several videos I would say.
Q. Are these -- were you provided videos or did you access them on YouTube or where did you see these videos?
A. Several times on the conferences, videos have been presented there how to do it and there I had the opportunity

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to see this and I got some for this litigation.
Q. From Mr. Anderson?
A. Yes.
Q. Have you seen videotapes showing how surgeons are instructed to use Ethicon TVT® classic mesh for the treatment of stress urinary incontinence?
A. Yes.
Q. What is your understanding about how a surgeon is to place the Ethicon mesh for the treatment of stress urinary incontinence, where and how?
MR. ANDERSON: Objection. Outside the scope of the opinions being offered in this case.
THE WITNESS: I've not the knowledge to discuss any or to give comments to any details of this procedure.
QUESTIONS BY MR. THOMAS:
Q. Do you know how -- strike that.
Do you know the mechanism by which the Ethicon mesh treats stress urinary

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incontinence?
Do you know how it works?
A. I know a lot of ideas that have been developed to get an understanding why this -- why this works and why this doesn't work sometimes. So a lot of ideas to understand this, but I don't know one way how it works.
Q. What's your best understanding as you sit here today about how Ethicon mesh used for the treatment of stress urinary incontinence works?
MR. ANDERSON: Same objection.
THE WITNESS: So far I understood that the sling provides a relaxation of this area at certain strain of the patient so that you have this tendency to -- that you have these changes in the function of the bladder and the sphincters and if you can provide a resistance there by this textile and the -- and the scarring process around this textile.

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QUESTIONS BY MR. THOMAS:
Q. What role do you understand mesh has on the sphincter?
MR. ANDERSON: Objection. Outside the scope of his opinions.
Go ahead.
THE WITNESS: I know that there are several other experts saying that it is not a -- that it shouldn't impact the sphincter at all, but should be in the midurethral area, but it is a huge field and it is not my topic to --
QUESTIONS BY MR. THOMAS:
Q. That's fine.
Do you have any information about how the mesh relates to the bladder for the control of stress urinary incontinence?
MR. ANDERSON: Same objection.
THE WITNESS: Yeah, in general, I have an impression where the sling is, that it's not directly interfering with the wall of the bladder, but, again, this is not the center of my

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work to identify the anatomy or the structures in the pelvic area.
We worked a lot of it, but I'm not prepared to give you a specific analysis of it.
QUESTIONS BY MR. THOMAS:
Q. Can you tell me anything about what the mesh does to treat stress urinary incontinence?
MR. ANDERSON: Same objections.
THE WITNESS: Roughly we assume that with the providence of a nonabsorbable permanent textile structure you have a reenforcement of these tissues around the midurethra, and this is a some sort of counterforce when the pelvis is going down. So, therefore, this is compensating these forces and thereby it improves the situation.
QUESTIONS BY MR. THOMAS:
Q. Do you know mechanistically how mesh used for the treatment of stress urinary incontinence improves the situation as you've

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described it?
A. As I told you, there are a lot of discussions how it definitely works and I just reflect that there are controversials about the definite mechanism, and I cannot provide you the one mechanistic solution.
Q. Do you have any understanding about whether mesh used for the treatment of stress urinary incontinence provides support to the urethra?
MR. ANDERSON: Same objections.
Go ahead.
THE WITNESS: Of course, it supports the tissue area there. It shouldn't be close to the urethra, but, of course, it supports this -- the urethra and this tissue as well.
QUESTIONS BY MR. THOMAS:
Q. You said it shouldn't be close to the urethra.
How close should it be at the most?
MR. ANDERSON: Same objections.
THE WITNESS: If it's very

close, there's a high risk for erosion.
QUESTIONS BY MR. THOMAS:
Q. Okay. So based on your training and education and experience, how far away should a surgeon place the mesh in order to protect against erosion?
MR. ANDERSON: Same objection. His experience -- training, education and experience, as he has told you, has nothing to do with the treatment of SUI.
THE WITNESS: I have no experience to give you some comment on this. I know it is a problem for the surgeons doing this procedure.
QUESTIONS BY MR. THOMAS:
Q. What's a problem?
MR. ANDERSON: Same objections.
THE WITNESS: That in some patients you have a damage of the urethra later on.
QUESTIONS BY MR. THOMAS:
Q. Do you know in what percentage

of patients that happens in the placement of mesh for stress urinary incontinence?
MR. ANDERSON: Same objections.
THE WITNESS: No, not -- I don't recall. I've read it, of course, but I don't recall in the moment.
QUESTIONS BY MR. THOMAS:
Q. Do you know from your research in this case where relative to the urethra the surgeon is instructed to place the mesh?
MR. ANDERSON: Same objections.
THE WITNESS: I know this from the video, what is said there, but I've not the expertise to do this procedure or to give a comment on this.
QUESTIONS BY MR. THOMAS:
Q. What do you recall from the video about the placement of the mesh relative to the urethra?
MR. ANDERSON: Same objections.
THE WITNESS: That it should be placed right and left to this and

there has to be a distance. So I'm not able to recall and to replay the video and I didn't never tried to do so.
QUESTIONS BY MR. THOMAS:
Q. Do you have any understanding about whether the mesh -- strike that.
Do you have any understanding about whether the Ethicon TVT® mesh used for the treatment of stress urinary incontinence is designed to provide support for the urethra?
MR. ANDERSON: Same objections. He's not being offered as a urogynecologist or a urologist.
Answer his question, if you can.
THE WITNESS: I only have a very limited -- no, I -- if you address that problem whether it's designed for the use as a sling, I cannot remember very good -- no, I cannot remember in the documents that there was a specific design for this

purpose that is used for the reenforcement of this area. As I told you, yes, there is a risk of the damage of the urethra, yes, by the surgeon immediately, that is one sort of damage.
The other is after two or three years you may have this damage and this is a problem with the material. So these are -- has to be separated in this discussion that the mesh material is specifically designed for this purpose. I don't get any data that confirms this.
QUESTIONS BY MR. THOMAS:
Q. Doctor, let's go to page 28 of Exhibit 11.
Page 28 of Exhibit 11 deals with that portion of your opinion that addresses mesh contraction.
On page 29, you have a Figure 7 which is a photograph of a mesh explant.
Is that a hernia mesh explant?
A. It is a mesh that we used in

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hernia.
Q. What kind of mesh is that?
A. I have to recall. It's either Prolene® or it's Marlex. I guess it's Marlex. I know it's written in the document, but I don't recall it.
Q. Okay. On page 30, Figure 8, again, Figure 8 is a hernia mesh?
A. Yes.
Q. And do you know what kind of hernia mesh that is?
A. It is a composite of polypropylene and the ePTFE.
Q. And who makes that mesh? Is it called a Kugel mesh?
A. Kugel mesh.
Q. And that's a BARD product?
A. I think so, yeah.
Q. And Figure 9 A, that's an explanted Prolift® mesh that apparently you've taken from the International Urogynecological Journal; is that correct?
A. Yes.
Q. And Prolift® mesh is a

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different kind of mesh than what is used in the treatment of stress urinary incontinence, isn't it?
A. Yes.
Q. It's called Prolene® Soft?
A. Yes.
Q. And page 31, Figure 9 B is a photograph of what's described in footnote 121 as the Carolyn Lewis explant photos.
Is that correct?
A. Yes.
Q. Did you ever observe other than by photographs the actual explant of Carolyn Lewis?
A. No.
Q. So do you have other photographs of the mesh explant in addition to the one that's in 9 B?
A. I do not recall.
Q. Did you make any effort to use the photograph in paragraph 9 B to analyze the condition of the mesh?
A. No. And I'm convinced it is not possible to make any further analysis

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from this image.
Q. Okay. Why?
A. The placement of these mesh particles, it depends from how it -- what happens during the OR, how it's done, how it's taken, how it was handled. There's no protocol how to handle all of these mesh materials there to remove this so, therefore, every further finding when you try to measure something here, it will be very hard to impossible to get a good interpretation of this.
Q. It's fair to understand that after a mesh is explanted, a person needs to know how the mesh is handled at every step before your analysis so that you can understand the extent to which the explant may have been altered, fair?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: It depends from the question you further on have.
If you just want to know if there are some specific cells at the

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interface, it is not important to know where it's explanted or so.
So it very -- it depends from where you're looking at whether this is affected by the handling of the surgeon.
QUESTIONS BY MR. THOMAS:
Q. Was it important to you in your work in this case that the mesh that was provided to you for analysis had been cut prior to being sent to you?
A. Cut in sections, in histological sections?
Q. Yes.
A. The fact that I was provided only the histological cut that gives some limitations to the analysis, of course. So you are restricted to what you see there.
Q. Other than the image that's on page 31 of your report and the histological cuts that you've just described, were you provided any other information related to the explant of Mrs. Lewis?
A. I've seen the report during the

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operation by the surgeon.
Q. Okay.
A. And the pathology statement from the hospital. So some medical records.
Q. Other than the operating room report and the pathology report from the hospital after the explant, do you recall receiving any other information about Carolyn Lewis?
A. Yeah, I recall 10, 11 files with medical records to various extents and thousands of pages with lab results and post-analysis and --
Q. Okay. Did you understand that you received, to the extent that it was available, her medical history?
A. Yes.
Q. Okay. So is it fair to conclude, Doctor, that you didn't analyze the mesh that's on -- in the photograph on Figure 9 B on page 31 of your report to determine the extent to which the mesh contracted?
MR. ANDERSON: Objection.

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Go ahead.
THE WITNESS: I didn't analyze it on the basis of this microscopical image.
QUESTIONS BY MR. THOMAS:
Q. Do you have an opinion to a reasonable degree of scientific certainty that Ethicon TVT® mesh used for the treatment of stress urinary incontinence contracts after implantation?
A. To make it clear in advance, I know that polymer itself does not contract and polypropylene does not contract itself. It is contraction of the wound area. It's a contraction of the collagen. It is a change of the tissue there. To be clear in this field, otherwise everyone can say a plastic sheet doesn't contract.
So in this regard that the scar shows some contraction and with this scar contracts the mesh, yes, it depends. In principle, the extent of contraction is related to the extent of scar formation and Prolene® induces a lot of scar formation and,

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therefore, yeah, you have a high risk for shrinkage and contraction. We know -- to say it already here, we know that there are some patients where it's less and there are other patients where it's more pronounced.
But what we have learned in these 20 years is that Prolene®, with its structure, with its weight, with its amount of material, it's a high risk for contraction.
QUESTIONS BY MR. THOMAS:
Q. In your 20 years of research, have you specifically studied the extent to which Ethicon Prolene® mesh used in the treatment of stress urinary incontinence contracts in vivo in the stress urinary incontinence application specifically?
A. We did not make our preclinical experimental studies to this topic, but I know that my clinical colleagues made some ultrasound investigation looking into the slings that Dr. Tunn in Berlin has done it, that there is -- there are some references showing that you can -- that you can analyze

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the degree of contraction in patients as well and that you find there some narrowing of the width of the sling.
Q. Have your clinical colleagues published any study describing their experience of contraction?
A. There has been a presentation, I think, at an international Congress and at the -- at a German conference where they presented their results.
Q. Do you know if the results that your clinical colleagues found have been published anywhere outside of this presentation?
A. At least the European or the international abstract has been published in the supplements there.
Q. Who are your colleagues so if I wanted to find that abstract I could find it?
A. Professor Kirschner-Hermanns, was a coauthor, Dr. Najjari, she made the study.
Q. Do you cite that abstract in your report?

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You know, I don't need to know.
You mentioned some work by Dr. Tunn in this area.
A. Dr. Tunn, yeah. We call it -- he has published studies using ultrasound looking what happens to meshes there, and I think it was -- it were one of the first articles published showing that there is this change of the mesh structure which was quite common in hernia surgery, we know it ten years longer, but for the urogynecologists, it was a new message at that time, I believe.
Q. Now, was his study published in a journal?
A. It was published in a journal. I don't recall precisely whether he was focused on meshes, the flat meshes, the Prolift® things, or whether he really looked to the slings or whether he combined it. I don't recall the details any longer, but he showed very clearly that using a textile in the pelvic floor as well you have these changes what we have seen in hernia surgery years ago.

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Q. Do you recall the extent to which Dr. Tunn found contraction in the study that he conducted?
A. Significantly. 50 percent or more.
Q. And when you say "50 percent or more," does that mean that the tissues surrounding the mesh basically shrinks in half?
A. That is a good point because there is a mixup of all of these things. Whether it's a reduction of the area of 50 percent, then you have a smaller reduction in the lengths and in the sides. So sometimes they -- in the literature, it's -- they mention the reduction of the lengths, not of the area.
So it is very often not clear about it, but at least in our clinical study, they measured the widths of the sling so it is clear it is in one dimension.
Q. Okay. Now, on page 33 of your report, in the middle of the page it says, "It also is my opinion to a reasonable degree

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of medical and scientific certainty that the Prolene® mesh in Ethicon's TVT® products contracts or shrinks 30 to 50 percent after implantation.
Is that correct? Did I read that correctly?
A. Yes.
Q. Does that mean that every mesh implanted in a woman for the treatment of stress urinary incontinence is going to shrink at least 30 percent?
A. No, that is -- that is not -- that is not correct. I wouldn't expect this. We know that from all of these preclinical and clinical studies that has been done to address the issue of shrinkage, it, of course, is influenced by the textile structure, but it is influenced by the surgical trauma as well, which leads to scar, which leads to a contraction of this area.
So even the best mesh which probably does not induce any inflammation in this field will be in an area of scar that shows a contraction of about 15, 20 percent,

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if you have extended scar tissue. If you have a laparoscopic procedure where the surgical trauma is minimized, this can be less than 20 percent. When you have an open surgical trauma there, it should be in around 20 percent. I would expect that this is a range that will be very hard to come below this range.
Q. For any --
A. Everything -- yeah, it is a consequence of the surgery and of scar. If you create some scar, you have it. If you produce a lot of scar, this shrinkage rate can go up to 80 or 90 percent.
Q. And when you use figures in your report of 30 to 50 percent or use numbers like you just used a moment ago of 80 to 90 percent shrinkage, what does that mean?
MR. ANDERSON: Other than what he's already told you?
MR. THOMAS: Well, he told me there's a confusion in the literature about how it was measured and I want to know what he means.

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MR. ANDERSON: Well, he told you more than that, but go ahead.

THE WITNESS: So we started when we first made revision operations and looked to all of these old meshes. We took a lot of photographs where we took the images of the mesh when it was implanted, we got a size of it and then later on at the revision you see that only a small -- a much smaller mesh because of the contraction. And that was the extent of shrinkage at that time.

Amid at the Suvretta meetings, he reported of a shrinkage rate of 80 to 90 percent for the plaques which are very big amount of material in a small place so this is the upper limit 80 to 90 percent of this. When we made our own experiments where we tried to figure out and we were still busy to work on it to objectify the extent of the shrinkage under various conditions.

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QUESTIONS BY MR. THOMAS:

Q. Are you currently involved in a study analyzing the extent to which the tissue around mesh shrinks or contracts?

A. Yeah. We have a study in the groin to look what happens to the mesh material after one year and specifically with the focus on shrinkage.

Q. Okay. And we talked about that yesterday?

A. Yeah.

Q. Have you ever conducted a study to determine the extent to which the tissues surrounding mesh after implantation for the treatment of stress urinary incontinence contracts?

A. We did a lot of these studies with Prolene®, with Marlex, which is the mesh that is used for the treatment of.

Q. I'm talking -- I am sorry.

A. But we didn't make specific analysis which reflects the treatment with a sling in the pelvic.

Q. Okay. So is it fair to

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understand that based on your training, education and experience that the use of mesh in any application will induce a shrinkage or contracture of 20 percent?

A. Not in the meaning that the mesh makes a shrinkage of 20 percent. It depends from the type of mesh. There are some meshes which usually lead to shrinkage that is 30 to 50 to 60 to 80 to 90 percent so.

Q. I get that.

My question is: Is the best that you can do when you use mesh in the human body is to have a shrinkage or contracture rate of 20 percent?

MR. ANDERSON: Objection. Asked and answered.

Go ahead.

THE WITNESS: As I told you, it depends. It's influenced by the surgical trauma as well. If you have a very, very small surgical trauma and very little scar formation, there may be. I can't imagine that you can go

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below this range.

QUESTIONS BY MR. THOMAS:

Q. "This range" being what?

A. Of 20 percent but, yeah.

Q. Okay. In how many patients who receive Ethicon TVT® products do you expect to see a shrinkage rate of 30 percent?

A. You cannot answer. It depends from the time period. It depends from the conditions of the OR. It depends whether there is a contamination with bacteria. It depends from the degree of the inflammatory process. So hopefully the number is quite low, but even if it's low, if it's not necessary, it should be avoided.

Q. In how many patients who receive Ethicon mesh for the treatment of stress urinary incontinence would you expect to see a shrinkage or contracture of 50 percent after implantation?

A. I can't give you a figure.

Q. Is that a common finding, a rare finding? Do you have any kind of range at all to attach to that number?

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MR. ANDERSON: Objection as to form.
Go ahead.
THE WITNESS: Again, it depends from the subgroup which you analyze and the time period. If you're looking after two months, then you will not expect a significant shrinkage due to wound contraction and therefore, the function may be very well.
If you're going to -- if you're looking at two years, three years and you have a patient with increased problems in this area due to the scarring process, then the likelihood of finding a shrinkage is -- well considerably higher.
If you look to all of the patients that you are -- you have to think about in the moment. In this subgroup, I expect that the rate of the significant shrinkage is much higher than in those who doesn't have

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any problems.
QUESTIONS BY MR. THOMAS:
Q. Doctor, is it fair to understand that mesh shrinkage or contracture does not always lead to patient complications?
A. I would expect that there isn't a hundred percent correlation between shrinkage and complaints. However, what we have learned in all our work is shrinkage is another description of reality. It's an explanation of complaints in many patients.
Q. And when you performed hernia surgery, you understood that your mesh would shrink or contract, fair?
A. I expected a shrinkage of this area to some degree in every patient, yes.
Q. And the extent to which that shrinkage or contracture caused any complication in the patient depends on the surgeon's skill and the specific comorbidities of the plaintiff -- excuse me, of the patient; is that fair?
MR. ANDERSON: Objection.

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THE WITNESS: No, it doesn't depend on it. It is influenced on. So you can create some pain just by surgery. You don't need a mesh to create some pain. But if you have an excellent surgery, excellent patient and then you get a pain, then maybe it can be a problem of the mesh.
QUESTIONS BY MR. THOMAS:
Q. Well, my point is you discuss with the patient who is considering whether to have mesh implanted for hernia the fact that this mesh will contract and it may cause complications?
A. Yes, but we are able to tell them that we are using mesh material where this risks has been minimized.
Q. Okay. And to the extent that you're using a heavy-weight, small pore mesh for those repairs where still appropriate, you would have the same conversation, wouldn't you?
A. Similar conversation, but another list of risks and benefits.

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Q. What are the complications that you associate with shrinkage?
A. Shrinkage?
It is a considerably stiffening of the implant so that migration, erosion is related to this. It is an expression of that you have an intense scar formation there so the likelihood that you will get a very stiff material that is not any longer very close to the physiological requirement or physiological characteristics, properties of the surrounding tissue, it became a very stiff thing and, therefore, it causes complaints and pain just by restricting the mobility of the tissue. It expresses huge intensity of scar formation in this area so there is a high risk of getting entrapped nerves in this scar formation. It reduces the area of the mesh material. In the field of hernia surgery, you expect that the overlap is decreased and, therefore, the increase for recurrence is higher.
If you have a significant shrinkage for meshes, slings that have to

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withstand some forces, then you have a higher pressure to the cells because the contact area is reduced. Shrinkage means that you have an accumulation of material at a specific area so even the large pore constructions will change and switch to small pore constructions. This may be some.

Q. Do you have any idea of the rate of complications that are reported due to contracture or shrinkage in the placement of mesh for the treatment of stress urinary incontinence?

A. We had some figures where we can -- where we can estimate the increase of risk for pain for these heavy-weight, small pore meshes as Marlex, as Prolene®, which were used for the treatment of incontinence.

Q. Marlex is not used for the treatment of stress urinary incontinence, is it?

A. As these meshes that are used, Marlex, no, it's not used. But these are -- these are the group of meshes and Prolene® is one of the meshes that is used.

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I'm not sure whether you are sticking on the specific situation in the pelvic floor or whether you want to focus on Prolene®. Prolene® is a hernia mesh that is used for this purpose and, therefore, I can say for the Prolene® mesh there is a significantly increased risk for pain. There are some data about it.

Q. I'm talking more specifically than pelvic floor. I would like to know for the treatment of stress urinary incontinence whether you have any idea of the rate of complications that are reported due to contracture or shrinkage in the placement of mesh for the treatment of stress urinary incontinence?

MR. ANDERSON: Objection. Asked and answered.

Go ahead.

THE WITNESS: Independent from the mesh material, if you wanted to know some figures of the patients treated for incontinence, whether they have some problems, I can't give you

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the figures.

QUESTIONS BY MR. THOMAS:

Q. Okay. Doctor, do you have an opinion about the extent to which mesh contracture or shrinkage in patients who are being treated for stress urinary incontinence impacts the cure for stress urinary incontinence?

MR. ANDERSON: Objection to form.

THE WITNESS: It depends from the subgroup you're analyzing. If you're analyzing the patients that complains afterwards, you will find a significant ratio of patient that suffered from shrinkage and, therefore, developed these complications.

QUESTIONS BY MR. THOMAS:

Q. When you say "complaints," what kind of complaints are you talking about?

A. Pain, dysfunction of the bladder.

Q. Now, just so --

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A. Erosions.

Q. Just so we're clear, the treatment of stress urinary incontinence is designed to help a woman manage her bladder for lack of a better description, isn't that fair?

A. What?

Q. Strike that.

The treatment of stress urinary incontinence is designed to treat the involuntary discharge of urine?

A. Yes.

Q. With that goal of the treatment in mind, does mesh contracture or shrinkage have any impact on the ability of the mesh to treat that condition?

A. Shrinkage, from my opinion, will be one reason or is a fact that reflects the extent of scar formation and this will be one reason for bad results of this procedure.

Q. And when you say "bad results," in terms of the ultimate goal of treating the stress urinary incontinence, what would you expect?

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MR. ANDERSON: Objection to form.
THE WITNESS: I didn't -- I didn't understand what comparison you want to have.
QUESTIONS BY MR. THOMAS:
Q. Well, we understand the goal of using mesh to treat stress urinary incontinence is to manage the involuntary discharge of urine, correct?
A. Yes.
Q. If you have mesh contracture or shrinkage, how does that impact what the mesh does to treat the involuntary discharge of urine?
A. If you have a significant shrinkage, a significant scar formation in this area, then you can have pain, you can have a increase -- or migration and erosion of the urethra. You can have erosion in the vagina.
So all of these things can be the consequence of scar formation and shrinkage in this field.

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QUESTIONS BY MR. THOMAS:
Q. Do you know whether mesh contracture or shrinkage impacts the ability of the patient receiving the mesh to control her urine?
A. I didn't -- please rephrase it.
Q. Do you know whether mesh contracture or shrinkage controls -- strike that.
Do you know whether mesh contracture or shrinkage impacts the ability of the patient receiving the mesh to control her urine?
A. I expect that considerable shrinkage of the mesh can in some patients lead to the -- or to a recurrence of the incontinence.
Q. Okay. So you would expect the incontinence to return. Mechanistically, how does that happen?
A. I have the impression that we're back some two hours ago. There is a complex interaction between the ligaments, the muscles of the pelvic floor. It's a very

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complex system, and if you have a very strict scar there that may be too small, that this impairs the dynamic of the pelvic floor significantly and, therefore, the function of all of the organs that are in the pelvic floor.
MR. ANDERSON: It's my turn to take a break.
MR. THOMAS: Sure.
(Off the record at 11:23 a.m.)
QUESTIONS BY MR. THOMAS:
Q. Doctor, during the development of VYPRO I, did you have any involvement in the biocapability analysis of VYPRO I?
A. Yes.
Q. And were there tests conducted on VYPRO I for carcinogenicity, for example?
A. If you think -- if you're thinking of some in vitro tests for -- I do not recall whether these tests have been done in Aachen.
If you're thinking of the general discussion about whether there is a risk for cancer when using textiles, we made

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investigations.
Q. Okay. Did you make investigations -- strike that.
Do you recall conducting any in vitro testing for VYPRO I?
A. In vitro testing we did it for the attachment of bacteria. We did it for the -- for the -- we did it in a setting where we looked what happens to the fibroblasts when growing together with meshes in vitro. That has been our studies, yeah.
Q. Did you conduct any cytotoxicity testing for VYPRO I?
A. Not that I recall.
Q. Do you recall learning that VYPRO I tested positive for cytotoxicity in vitro?
MR. ANDERSON: Objection. Based on his prior answer.
Go ahead.
THE WITNESS: I recall that somewhere in the documents there has been some -- there has been done some in vitro cytotoxicity tests indicating

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that polypropylene has some problems, but I do not recall any specific investigations to the VYPRO that is done in Aachen. I'm sure it will be done or it was done in Hamburg Ethicon because it's required before launching a product to the market.

QUESTIONS BY MR. THOMAS:

Q. And my question is simply this: Whether you did the testing or not, did you ever learn from any source that VYPRO I tested positive for cytotoxicity in vitro during the biocompatibility analysis?

A. Not that I recall.

Q. About an hour ago, maybe more, you mentioned a recent study in the last year involving PVDF mesh and I thought I understood you to say it was a comparative study.

Do you recall that testimony?

A. I mentioned a study with PVDF?

Q. And I want to say, my notes are very sketchy on it, I tried to write it down so I could remember, but I thought it was a

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comparative study involving PVDF meshes perhaps out of Berlin.

MR. ANDERSON: He's asking you if earlier in your testimony did you -- were you talking about some comparative study involving PVDF meshes out of Berlin.

THE WITNESS: In the pelvic floor?

QUESTIONS BY MR. THOMAS:

Q. Anywhere. Pelvic floor, hernia, I'm not sure.

A. Comparative in the meaning that you compared different materials and one of it is PVDF?

Q. Yes.

A. No, I don't recall any clinical study.

Q. Okay. Since your deposition last year, are you aware of any clinical studies that compare the risks and complications associated between PVDF and polypropylene?

A. Now I got it. You may refer to

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this study that is done by our gynecologist, Dr. Najjari, who made ultrasound investigation comparing two different slings, one of polypropylene and one of PVDF, and they presented these results in this abstract that has been published in this supplement article.

Q. Other than that study that you just described, since your last deposition in October 2012, are you aware of any clinical studies that compare the use of PVDF to the use of polypropylene in any application to determine which is better?

A. No, I don't recall any clinical study.

Q. Doctor, what have you done to analyze the forces that are placed upon mesh used for the treatment of stress urinary incontinence?

A. It started with our efforts to get a first impression about forces to the mesh materials in principle, how to define it, how to measure it, how to get a range, a figure out, and these efforts started in 1993

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with this question. And in 1994, we started to think about how to define the forces, the requirements to the textiles for the reenforcement in tissues.

So that was the -- that is the rough experience that we got during all these years that we got an impression of the range and what can be considered as over engineered and whatnot.

In 2005, '6, the upcoming question was what are the biomechanical properties to the pelvic floor and we tried to -- or we made -- we looked very careful to the literature, Cosson and all of these expressed what they are considering for the use in the pelvic floor and so we tried to combine all of this knowledge to get an impression.

Q. Okay. So what specifically have you done to analyze the forces that are placed upon mesh used for the treatment of stress urinary incontinence?

A. As I tried to answer it before, we analyzed a lot of these data that have

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been there. We analyzed very careful the difficulties to find a good equipment, a good setting, to come to a specific data there. And finally we got an impression about the biomechanics, the differences of the biomechanics between the pelvic floor and the abdominal wall. We didn't do any specific measurements as Cosson did, yeah.

Q. When you're talking about forces in the pelvic floor, are you talking about forces that occur in the pelvic floor in the management of pelvic organ prolapse?

A. It is not limited to the pelvic -- it is not limited to the prolapse. It is -- when we have been studying the biomechanics of the pelvic floor, what happens there, the intention of this was to define what may be the requirements of the textile in regard to stability. That was the purpose for this. Not to simulate or to reflect the situation there and, therefore, we focused mainly on some forces per centimeters and, yeah, we know that there are -- or I know that there is a -- that it's

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very difficult to define really the biomechanics in the pelvic floor. It is impossible to get all aspects there.

So force is one aspect, but we focused on the force -- what is important for the characterization of the mesh material, of the textiles there.

Q. And what forces did you study to determine the requirements for textiles in the pelvic floor, what forces did you study?

A. The forces -- the basis of our -- of my opinion about the -- it is based on the experience that tissue has some limited ability to withstand some forces so any repair has to consider that the surrounding tissue is limited in this field.

You have to consider some intraabdominal pressure, that you have to consider some flexibility of the anatomic structures. We have made some measurements tearing out looking at what is the resistance of tissues to extract meshes or sutures or anchors what are the forces there. We made some analysis of textile structures, what are

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forces, what is elasticity that can be done there.

So a lot of various things to get a closer idea about the biomechanics of the pelvis.

Q. What specifically have you done to measure the forces that are applied to mesh that are used for the treatment of stress urinary incontinence?

A. We never made direct measurements of the forces.

Q. Have you reached any opinions about the nature and the extent of the force that's applied to the mesh used for the treatment of stress urinary incontinence?

A. So in conclusion of all these -- our experiences and all of the literature there, it is -- it is -- I'm sure it is in a range that is far below the tensile strength that is required for the abdominal wall so it is less about 10 newton per centimeters. Yeah, less than 10 newton per centimeters I would expect.

Q. And when you say 10 newtons per

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centimeter, what does that measure?

A. That means that's the force per centimeter of the textile. I know there's a mixing up, and I recall a very precise summary of this mixing up by Professor Williams. At the last deposition, he made an expert report where he summarized the mixing up of pressures force per centimeters and forces, per se. That cannot be interfered or that cannot be exchanged so this figure is limited to newton per centimeter, that means per centimeter of mesh in the width end or tissue.

Q. And when you speak about force, in what direction is it applied?

A. It's a uniaxial force.

Q. And from what direction is it applied?

MR. ANDERSON: Objection to form.

THE WITNESS: It is a -- first of all, it is an abstract direction -- yeah. No, it's theoretical assumption without having a specific direction.

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When you estimate the tensile strengths that is necessary to reinforce abdominal wall of the pelvic floor, there is no specific direction. If you made a measurement at the textile, indeed you have to make separate analysis in meshing direction and perpendicular to the machine direction then you will get different results.

But to define the -- an estimate of the maximum of the requirement -- maximum or minimum requirements, then there is no direction.

QUESTIONS BY MR. THOMAS:

Q. Okay. You said a moment ago that the force was uniaxial.

What do you mean by that?

A. Uniaxial is the experimental setting that you fix the mesh or the sample -- tissue sample or mesh sample on one side and your tearing on the other and then you get a force. And if it's a stripe with

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widths of 1 centimeter, you get some figure. If it's 2 centimeters, you get another figure.

To easy up the comparison of different structures, later on it is normalized to a width of 1 centimeter, though, in fact, these measurements are all done at various widths of the sample size, 4 centimeters, 5 centimeters. There are different standards. Usually it's described in the material and methods.

Q. And the uniaxial testing you're describing now, is that used by yourself and Dr. Mühl in your study, Exhibit 20; is that correct?

A. This uniaxial testing is part of these measurements of Professor Mühl, but we started in 1994 with our first textile analysis to provide this data.

Q. Back in 2008, 2007, when Exhibit Number 20 was published, the last sentence of the abstract says, "Further, in vivo studies have to investigate whether the preservation of a high effective porosity

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under stress may help to improve biocompatibility of textile implants."

Has there been any further in vitro -- have there been any further in vivo studies to investigate whether the preservation of a high effective porosity under stress may help to improve the biocompatibility of textile implants?

A. Can I have a look?

As we discussed yesterday, the -- a difficult or an important point is to identify the impact of these effective porosity on the clinical outcome, how to identify this. And, yes, indeed there -- we meanwhile know that there are various mesh materials. We try to get precise data of the effective porosity of the various kinds of materials and we want to analyze registries in regard to these properties of the mesh materials. These are the studies we're working on in the moment. So, yes, there are attempts to make clinical studies.

Q. But there haven't been any published yet --

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A. No. No. No.

Q. Let me get my question out.

A. Yes.

Q. There haven't been any studies -- strike that.

There haven't been any in vivo studies which investigate whether the preservation of a high effective porosity under stress may help to improve the biocompatibility of textile implants; is that correct?

A. Yes.

Q. Now, we talked earlier about how the mesh is placed in the body.

It's not anchored or secured on either end?

A. That is correct.

Q. And the way the mesh holds its position in the body is by the tissue moving through the pores and anchoring the pores, correct?

A. If you restrict it to the time period directly after the operation, this is for the first seconds or minutes, this is the

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major mechanism, I suppose. Later on, it will be replaced by others.

Q. When there are forces applied to the mesh after implantation, the mesh can move with the forces, can't it?

A. If you apply some forces to a mesh, then, first of all, you have some sheering stress at the area where the forces is applied.

So the assumption that the entire mesh as a block moves accordingly to some forces somewhere, I think this is not a true, realistic image.

Q. Okay. In hernia repair, you often anchor the mesh, suture it; is that fair?

A. Fixation of meshes for incisional hernia, it is not necessary. When you place a mesh in the retro muscular position, it is not necessary to do any fixation anymore. If you make a TP repair and you place a mesh there, there's no need for making any further fixation there. If you make a TAPP, you increasingly use glue --

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which Fibrin glue from Ethicon, for example, that sticks there or fixed there the mesh for some days or hours. So short-term fixation there.

It depends on the position. It depends -- IPOM mesh usually have to get a fixation. It is a -- yeah, it is a difficult question there.

Q. Okay.

A. It depends on the mesh and on the localization on the patient, on the surgeon.

Q. Uniaxial loading means just as you described it. You have one end of the mesh stable and you pull the other end, correct?

A. It's not necessary that one end is stable even if you have a textile like this and you're tearing from both sides, it's uniaxial.

Q. Okay. And what are the forces underneath the urethra that cause the uniaxial loading that you've just described?

A. To my knowledge, there isn't

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any precise measurements of this that does not interfere with the -- with the procedure.

In general, you have to expect that by the movement of the urethra, by some physiological movements, standing up or pressing or so, or the movements of the pelvic floor, that you have some shifting of the position of these -- of these organs in relation to other -- to the bony structures.

And this shifting, this mobility, this movements, they will lead to some locally forces.

Q. And those forces will come from multiple directions, won't they?

A. Always. Always they will come to -- from all directions, from all three directions, but to get a good estimate to get an idea of the model to evaluate a device or to construct a device, I am sure that for slings it is a reasonable and acceptable compromise to think that the uniaxial is more important.

Q. And on what do you rely for that statement?

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A. On our experience, the literature.

Q. In hernia repair?

A. Textile. Not hernia repair. It's a use of textiles for the reenforcement of tissues.

Q. Okay. Specifically, Doctor, have you analyzed the forces that are present in the area of the body where the mesh is placed for the treatment of stress urinary incontinence?

A. Whether I've analyzed these forces?

Q. Yes.

A. Only in the way that I try to express looking to the literature, looking to -- making some measurements at textiles to see whether it's comparable or not.

Q. Can you point me to any literature or research upon which you rely specifically identifying the forces that are present in the area where the mesh is placed for the treatment of stress urinary incontinence?

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A. I recently found a publication from 1995, I guess, where they placed at the time before TVT®, they -- at the time, they placed fascia slings around the urethra and there they measured the force there.
Q. Do you remember the name of that study?
A. Not at the moment.
Q. Did you find that information to be valuable, important to you?
A. It was just recently that I found it, but it was a confirmation of these estimates.
Q. Okay.
A. Because it was less than these 10 newtons.
Q. And do you recall what that study that you found looked at and what it found?
A. They measured in patients with a device the force at both sides of these fascia sling that the force that was necessary to make a narrowing of the urethra.
Q. Okay.

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A. So they got an in vivo force there.
Q. Okay. So anything other than this 1995 study that you recently reviewed upon which you rely for the forces that are present in the area of the body where mesh is placed for the treatment of stress urinary incontinence?
A. Look to a lot of these references, but from my memory, the Deprest working group with Ozon -- I think Ozon is his name, they presented two, three extended thesis, documents where they presented a lot of data, what they measured and what they calculate, what they estimate.
Q. Okay.
A. For the pelvic floor area.
Q. Okay. Now, did -- is Cosson, is that what you said or Deprest?
A. Yeah, Cosson made a lot of measurements at the tissue, but it was from Leuven, Deprest, yeah. This working group there.
Q. The working group that you just

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described, did they provide any measurements of the forces in the body at the place where the mesh is used for the treatment of stress urinary incontinence?
A. They made some -- as I recall, they made some estimates of the tensile forces that should be considered for the reenforcement of pelvic floor area.
Q. Now, I'm not talking about reenforcement of pelvic floor.
I'm talking very specifically about mesh placement for the treatment of stress urinary incontinence.
A. I don't recall that they have a specific chapter dealing with slings.
Q. Okay. So we're back to the 1995 study.
Is there any other study to which you can point me in support of the -- your understanding of the forces in the body at the place where the mesh is used for the treatment of stress urinary incontinence?
A. There maybe -- maybe some others, but I don't recall. But these --

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this is -- to my knowledge, this is the only one who really measured the forces.
Q. And just so the record is clear, you have not conducted your own analysis of the forces in the body at the place where mesh is used for the treatment of stress urinary incontinence; is that true?
A. That is true, I didn't do it.
Q. Okay. Now, when you use the term "uniaxial loading," you were referring to forces purely coming from one end to the other of the mesh; is that correct?
A. That is correct.
Q. Seems to me that if mesh is placed across a woman to support the urethra for the treatment of stress urinary incontinence, that there will be forces from the back to the front of the mesh as well; is that true?
MR. ANDERSON: Objection to the form of that question.
THE WITNESS: If you're talking about forces that happens in the pelvic floor area, you're right.

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There are various forces for the various structures.
QUESTIONS BY MR. THOMAS:
Q. So the basis of your opinion is that the predominant force is uniaxial; is that fair?
A. In a sling, the assumption that the uniaxial force is an important issue, yes, that is true.
Q. Okay. How does the body apply a uniaxial force to a sling?
A. If you place -- in contrast to meshes which are flat meshes with a wide area of tissue integration, when you make small slings, not 20 centimeters, but 1 centimeter, and this is 20-centimeter long there and you made or placed a sling from the lower part of the pelvis to the skin there, that if you have some movement there in this direction --
Q. You're moving down?
A. Down, yeah.
If the pelvic floor is going downwards, I expect that most of the forces, the strain, is going in the similar direction

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where the sling is located. And if you compare the movements going down, they are -- or they are in relation to the widths of the textile, they are -- they are higher than the mobility in these two directions.
Q. Okay.
A. You only have 1 centimeter of width. If you have a tensile force trying to make this wider, it's a very small effect.
Q. Okay. So as I understand your answer, please correct me if I am wrong, a downward force perpendicular to the placement of the mesh will cause a uniaxial loading on the mesh; is that correct?
MR. ANDERSON: Objection to form. Mischaracterizes his testimony.
THE WITNESS: What I wanted to express is that you place a sling, that the uniaxial strain to this sling in the direction of the sling, that is more relevant than the strain from the sides.
QUESTIONS BY MR. THOMAS:
Q. Okay. Uniaxial loading by

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definition means you're pulling on each end, correct?
A. Or you made a fixation at one end. It is uniaxial, it is just in one direction.
Q. And the force that you just described, if you have a mesh in a straight line, the force that you're describing comes from above is down on top of the mesh; is that correct?
MR. ANDERSON: Objection. Form.
THE WITNESS: However -- the result is that the sling, the ligament, is stretched.
QUESTIONS BY MR. THOMAS:
Q. I understand.
A. And that makes an uniaxial strain.
Q. But the force you're describing is not at the end, it's from the top down on the mesh, correct?
A. Yes.
Q. And so when the force comes

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down on top of the mesh, there is a force into the pore structure of the mesh, correct?
MR. ANDERSON: Objection.
Do you understand his question?
THE WITNESS: Yeah. Yeah, but I just -- in principle, yes, there's force, but what is the force, how big is the force. It depends on the surface, it depends from the cells. As a scientist, I usually try to then to measure it. I think it is impossible. There is a force, yes, but I think it is -- I'm sure it is a -- in an area where it's almost impossible to measure because it's so low.
QUESTIONS BY MR. THOMAS:
Q. Let me ask you this question, Doctor.
A. And, therefore, not relevant so --
Q. Can you think of a circumstance in the body where a mesh used for the treatment of stress urinary incontinence is

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placed under stress by pulling one end against the other like you do in Exhibit 20?
A. Is placed under stress?
Q. In the same way that you did in the study which is Exhibit 20.
A. So far I understood is that the recommendations when implanting these slings, that this shouldn't be done by applying a huge amount of tension there. And I don't think that it's a good idea to place a mesh wherever under tension.
Q. So my question is this, Doctor. I'm trying to understand whether you can identify for me any force in the body that is uniaxial in nature that replicates the forces that you and Professor Mühl used in your study, Exhibit 20.
MR. ANDERSON: By that you mean uniaxial forces?
MR. THOMAS: Yes.
MR. ANDERSON: Okay.
THE WITNESS: Whether I can identify these forces?

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QUESTIONS BY MR. THOMAS:
Q. Yes.
MR. ANDERSON: He said anywhere in the body where there are forces that are uniaxial, right?
MR. THOMAS: Okay. Let me ask the question again.
MR. ANDERSON: It's a little confusing. Yeah.
QUESTIONS BY MR. THOMAS:
Q. My question, Doctor, is this, I think: Can you describe for me forces in the area where mesh is placed for the treatment of stress urinary incontinence that replicate the forces that are used by you and Dr. Mühl in your study of effective porosity, which is Exhibit 20?
A. The first issue is whether there are some uniaxial strain there and if you look to the anatomy, you have some ligaments. Ligaments usually are thought to compensate uniaxial the mechanical strain, the biomechanics there, in contrast to some fascias or muscles there.

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So any procedure using textiles for the replacement of ligaments usually mainly has to address uniaxial forces. So textiles replacement of ligaments usually I think it is -- very acceptable to reduce this to an uniaxial model.
Q. Ligaments have forces and stresses in other directions, too, don't they?
A. As we told, there are always forces to some degree from every direction, but they are not significant. They are not relevant in comparison to the others. That's a reason that you have ligaments and not a muscle at that position.
Q. And my question, Doctor, is can you describe for me specifically those forces in the area where mesh is placed for the treatment of stress urinary incontinence that replicate this uniaxial loading?
MR. ANDERSON: Objection. He just answered it.
MR. THOMAS: He used a ligament as an example.

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MR. ANDERSON: Yeah.
THE WITNESS: If you look to the book of Petros, yeah, there are some sort of ligaments that are stabilizing the urethra, and if you use a textile as reenforcement of this weak structure to treat this patient, yeah, it should be considered as a replacement of a ligament. And even from the form, you're dealing now not with a flat mesh area, but with a 1 centimeter width. So that is the difference. 20 to 1 centimeter.
QUESTIONS BY MR. THOMAS:
Q. So it's your testimony that the forces that are applied to the mesh by the body are uniaxial in nature all the time?
MR. ANDERSON: Objection. Asked and answered.
THE WITNESS: No, that is not correct, not all time.
It is a justified assumption that it gives important information to have this testing in a uniaxial

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direction. It helps us to define -- to define the requirements to a textile which is intended to replace a ligament in this setting and then you have to define the range not to get the risk of being over engineered. And the Mühl testing just covers one -- some range within this.

QUESTIONS BY MR. THOMAS:

Q. For mesh that is implanted for the treatment of stress urinary incontinence, if a force is applied to the mesh, both ends of the mesh have the flexibility to move, don't they, with the tissue?

MR. ANDERSON: Objection to form.

THE WITNESS: Yes. They have the -- yeah.

QUESTIONS BY MR. THOMAS:

Q. Okay. In the test method that you and Dr. Mühl devised for the measure of the uniaxial loading, when you test the force to measure the effective porosity, one end of the mesh can't move, correct?

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A. Yes. And this leads to the question what period of implantation of mesh you want to get this information for.

If you're looking for the situation where the surgeon applies this material, he has to have it in his hands. So he fixed one immediately and that is a situation that is probably more closer to the testing.

Of course, there is another situation after three months, after one year when you have all of this tissue integration there and so.

Q. Let's go to page 59 of your report, please.

Right in the middle of the page you're talking about, "The danger of heavy-weight, small pore hernia mesh and its impact on tissue reaction when using the hernia mesh Prolene® for your gynecological slings," correct?

A. Yes.

Q. You say, "It is my opinion to a reasonable degree of medical and scientific certainty that there is no rational reason why the TVT® needs the stability and the amount of material of the Prolene® hernia mesh which can only be regarded as over engineered for this purpose."

Now, we've talked about that at length, haven't we?

A. Yes.

Q. You continue in your opinion, you say, "It should be mentioned that in the field of abdominal wall hernia repair, the use of large pore, light-weight meshes has become a standard recommended by guidelines and meta-analysis."

Why is it important to you that in the field of abdominal wall hernia repair the use of large pore, light-weight meshes has become a standard recommended by guidelines and meta-analysis?

A. Just to confirm that the fact that large pore textile constructions are widely accepted in the field of abdominal wall hernia surgery with all the history, and this is not only a fact that is indicated by some preclinical animal experiments, but it is widely accepted in the world of surgery that, yeah.

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Q. When you talk about a standard recommended by guidelines, to what are you referring there?

A. There are the European Hernia Society that has guidelines for the treatment of groin hernia, and they said that it is advantages to use a large pore, light-weight meshes. There is the International Endoscopic Hernia Society that has recently published guidelines for the treatment of endoscopic hernia repair and now for the treatment of laparoscopic incisional hernia repair under the guidance of Bittner, Professor Bittner, and they have a chapter, "Impact and Selection of Mesh Material," and there it is clearly expressed that large pore constructions have advantages and should be -- should be used and in these guidelines, you will find the references to the meta-analysis that has been published some in Hernia.

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I know that there are some meta-analysis coming to the result -- nonsignificant result -- difference, but more or less taking these meta-analysis and these guidelines. It is well-accepted in the society or in the field of hernia surgeon to use material reduced large pore meshes. It's no doubt about it. No -- yeah.

Q. No doubt about it based upon the standards you just identified --

A. Not based upon, but this -- these guidelines are reflecting the literature, the opinion of experts, there are different levels of recommendations. So it's not because of the guidelines, but the guidelines indicate that this acceptance of the surgeons.

Q. The meta-analysis studies the data, correct, and collects the data and draws conclusions from the existing studies?

A. Yes.

Q. And the guidelines to which you refer are the guidelines of the professional organizations who have experience in hernia

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surgery who are familiar with the literature and they publish as a professional organization their opinion as to the proper mesh to use in the hernia application?

A. I don't know whether I got the point. These are not professional organizations. These are organizations by surgeons. They have according to the protocol of the oxford community how to make guidelines. You have to make a reading of the literature. You have to classify the literature according to the level of evidence. You have to add the expert comments on it. You have to pass it several times around so that everyone can give his comment and finally you have some statements, what are the facts and then you have finally some recommendations.

And this is not a commercial thing that is our -- this is the enthusiasts trying to define the best therapy.

MR. THOMAS: Let's take a break for lunch.

MR. ANDERSON: Sounds good.

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(Off the record at 12:27 p.m.)

(Klinge Exhibit 22 marked for identification.)

QUESTIONS BY MR. THOMAS:

Q. Doctor, I hand you a document that's been marked as Deposition Exhibit Number 22.

Deposition Exhibit Number 22 is a section from a book called "Hernia Repair Sequela," written by Volker Schumpelick and Robert J. Fitzgibbons.

Is that Professor Schumpelick the same person that is your superior at your office at the university?

A. That was?

Q. Is that the same Schumpelick that you worked for at the university?

A. Yes. Yes.

Q. And who is Robert Fitzgibbons?

A. He is an American surgeon who is a co-editor for this work and the cochairman for this conference.

Both are editors of the Hernia Journal still additionally to Marc Miserez

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from Leuven. These three from it.

Q. And it says it's in collaboration with Joachim Conze; is that right?

A. Yes.

Q. And that's the same Dr. Conze that you worked with at the Aachen group?

A. Yes.

Q. I'm sure you're familiar with this chapter, aren't you?

A. Yes.

Q. If you turn to -- it's 2010.

The third page reads, "Alloplastic implants for the treatment of stress urinary incontinence and pelvic organ prolapse," shows you as a coauthor with -- and who are those people?

A. This was B. Schuessler, it's Professor Schuessler from Luzern. He's the head of the gynecological department there, and he's giving this presentation at the St. Moritz meeting. And T. Kavvadias is a coworker of this department who prepared the manuscript. It was a summarize -- or it's --

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the manuscript that should be printed and the content of the presentation of Professor Schuessler.

Q. Did you have any responsibility for the presentation of Professor Schuessler?

A. My relationship with Professor Schuessler is that we share a lot of ideas, a lot of knowledge. We prepare together some publications and, therefore, some of his ideas are reflecting our experiences in this -- in this meaning, yeah, I'm responsible for some of the contents he presented there.

Q. Okay. What responsibility did you have for the preparation of this chapter in this book?

A. I was asked when they prepared this manuscript as the basic content of the presentation of Professor Schuessler. They asked me to revise this manuscript because some of these aspects are mainly based on our work and our experience and, therefore, I was asked to give my comments and corrections to this manuscript. So I'm a coworker there.

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Q. If you turn to page 440 of Exhibit 22, that's a category that says, "Meshes in Stress Urinary Incontinence."

Do you see that?

A. Yes.

Q. Second paragraph says, "At present, the gold standard in SUI surgery is the suburethral sling, using tension-free vaginal tape, (TVT®) or the transobturator tape, (TOT) technique."

Do you agree with that statement?

A. I wouldn't have chosen it. We had similar discussion in our field of surgery is there any gold standard, what is a gold standard. I made several presentations about this. Today I wouldn't select the word "gold standard," but it is not -- I don't see that it is a serious mistake to use it in this context of this article.

Q. Okay. You see in the last paragraph of that column, right in the middle they're talking about "A prospective randomized control trial by Mechia so that

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vaginal erosion of Amid type III mesh used for intravaginal sling plasty was as high as 9 percent in a two-year follow-up, which is significantly higher compared to zero percent using the classical TVT®, type 1 macroporous monofilament polypropylene mesh in the same trial."

And that's the Johnson & Johnson mesh, Ethicon?

A. I guess I have seen the original publication to this, but it would be misleading to not to mention the first sentence, "Less erosion rates depend on the selection of the material" and, therefore, this study and this article confirms the finding of this study that there is an impact of the material on the clinical outcome and whether it's 9 or zero percent, 1, the power of this study is not sufficient.

Q. You stand by the language in this exhibit, don't you?

MR. ANDERSON: Objection.

THE WITNESS: I don't see any big conflicts of interest or big

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mistakes there.

QUESTIONS BY MR. THOMAS:

Q. What do you understand "gold standard" to mean?

A. Gold standard is a difficult word. I wouldn't use in the moment to define anything.

(Klinge Exhibit 23 marked for identification.)

QUESTIONS BY MR. THOMAS:

Q. Let me show you what I've marked as Deposition Exhibit Number 23.

Deposition Exhibit Number 23 is another study that you've been associated with.

You recognize this as the Klink study we talked about yesterday?

A. Uh-huh.

MR. ANDERSON: Yes?

THE WITNESS: Yes.

MR. ANDERSON: Thank you.

QUESTIONS BY MR. THOMAS:

Q. And this is a comparison of long-term biocompatibility of PVDF and

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polypropylene meshes, correct?
A. Yes.
Q. What role did you have in this study?
A. My role in this study was mainly to have a look to the data and to work on the manuscript with the interpretation and the presentation of this data.
Q. And all of the authors on this study are associated with the universities?
A. That's true.
Q. And what specialty or discipline does C.D. Klink have?
A. He's a journal -- he's a surgeon. He's a general surgeon.
Q. And Dr. Junge, what discipline or expertise does Dr. Junge have?
A. The expertise or the medical profession, he's a surgeon as well. His expertise is that he has been working since 1996, '7, I guess, in our group. We made a lot of different investigations there so he has a -- he's very familiar with all of these work what we have done.

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Q. And M. Binnebösel, who is that?
A. He's a surgical resident who later on came and mainly he worked in this field in the past five, six years.
Q. Who is the next person?
A. Dr. Alizai, he's a young resident. He has not finished his surgical training education and he's just at the beginning of his career.
Q. And how about the next person?
A. Dr. Otto, he is a surgeon. I think he has been -- he's finished his education as a surgeon. He's working scientifically for some years meanwhile and in our group, if you want to say, so he mainly is busy to investigate this visible mesh structures.
Q. And Dr. Neumann?
A. Professor Neumann is the head of the department.
Q. The department of surgery?
A. Of surgery.
Q. Took Professor Schumpelick's position?

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A. Yes.
Q. And what was the goal of the study?
A. The goal of the study was to see long-term differences between PVDF and polypropylene meshes.
Q. And the materials that you used for this study were supplied by FEG, correct?
A. Please let me have a look.
Q. It's on the second page under "Mesh Materials."
A. Yes.
Q. Do you know whether FEG provided those materials or you were required to purchase them?
A. I don't know.
Q. All right. And the mesh materials used in this study -- strike that.
One of the things that you also did in this study was to take scanning electron microscope images of the explant, correct?
A. Yes.
Q. And on page 294 of Exhibit 23,

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down under "Results," it says, "Exemplary electron microscopy of explanted samples revealed the signs of surface cracking of the polypropylene samples which were not detectable on the PVDF samples." And then on the right, there are images of what was found in the study, correct?
A. Yes.
Q. Dr. Klinge, have you discussed with FEG the fact that the polypropylene that they use in their mesh implants displays surface cracks such as are depicted in photograph 9 or page 294?
A. We discussed these results, yes.
Q. Did you discuss with FEG any risks that you saw to patients who received the mesh due to the surface cracking that appears in paragraph -- or picture A on page 294?
A. Not specifically.
Q. Have you discussed with FEG at any time any risks of danger to their patients because of surface cracking such as

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that depicted in picture A on page 294 of Exhibit 23?
A. We -- since we started to think of PVDF in 1998, we were working to figure out the advantages of PVDF. And, therefore, the study just to us was a confirmation of the findings from others and demonstrates the advantage of PVDF. I didn't -- yeah, that's it.
Q. Okay. FEG uses polypropylene in some of its implants, correct?
A. Yes.
Q. And you've been aware that FEG uses polypropylene in some of its implants for some time?
A. Yes.
Q. You've been aware that -- you understand from conversations with Clavé and Klosterhalfen and others, that there have been reports that surface of some polypropylene meshes show cracks?
A. Yes.
Q. Have you ever discussed with FEG any risks to their patients because of

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these observations of surface cracks?
A. It is -- I always make it clear and Bernd Klosterhalfen made it clear since 20 years that using polypropylene in comparison to PVDF has an increased risk, yes.
Q. Did you tell specifically FEG that the surface cracking in these photos presented a risk to their patients that received their mesh?
A. They know this, yes.
Q. My question is: Did you tell them that?
A. Yes, we -- yeah.
Q. And what did you tell them about the risk?
A. That there is a potential risk of this surface cracking that sometime it may be related to some increased inflammatory reaction, more infections. So we always told what is the consequence of a surface cracking. That is an increase of surface with all of the consequences and, therefore, this is an increased risk if you have a

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material that shows this.
Q. And who did you tell FEG about this increased risk?
MR. ANDERSON: Who did you tell -- who did you tell FEG?
QUESTIONS BY MR. THOMAS:
Q. Who did you tell at FEG about this increased risk from what you observed in this photograph on paragraph A on page 294?
A. To everyone. I'm sure everyone. All of the -- all of the people that are involved in this mesh design, that was it and I've discussed it with them.
Q. Dr. Obolensky?
A. Yes.
Q. Mr. Mullen?
A. Yes.
Q. Do you know whether FEG has ever taken any steps to warn the surgeons that use their products of any risk from degradation -- strike that.
Do you know whether FEG has ever taken any steps to warn the doctors who use their mesh about any risks from the

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surface cracking that's observed in paragraph A?
A. I'm not familiar. I'm not familiar with the legal things, what has to do something with warning here and informing.
My relationship to the FEG is that we together we're in favor of the PVDF and that's it. And they tried together with me to make more and more devices only of pure PVDF.
Q. You don't want to be associated with a product that creates a risk of harm to patients they don't know about, do you?
MR. ANDERSON: Objection to form.
THE WITNESS: I didn't understand this question.
QUESTIONS BY MR. THOMAS:
Q. You don't want to be associated with a product that creates a risk of harm to patients they don't know about, do you?
MR. ANDERSON: Objection to form.
THE WITNESS: You have to -- in

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Germany, you have to inform patients about risks with a rate of 1 to 10,000, so in this area.

In the moment, we have the information of a surface cracking since some years, five, six, seven years, and before the time we thought it was stable. We believed what they have seen there. So this is a recent finding and still today there are a lot of -- there are some people from the manufacturers and saying that is just an artifact. It's not a real complication. We know there are some potential risks by the increase of surface by this, but I cannot figure out what is an exact ratio. I even don't know what happens after 30 years, after 40 years.

Our experience up to now is that within the first two years, three years, there is no report about a ruptured degradated mesh material leading to a recurrence or to a

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clinical consequence.

We have no doubts that it happens, meanwhile the consequences has to be carefully surveyed during the next time.

QUESTIONS BY MR. THOMAS:

Q. You used the rate of one in 10,000. Do you have enough information available to you to determine whether the risk to a patient who receives a polypropylene mesh from FEG creates a risk greater than one in 10,000 that they will suffer adverse consequences because of that mesh?

A. My current opinion to this point is that at the moment we don't have sufficient data to quantify exactly the consequence of this finding to the clinical outcome. We don't have any doubt, there is no doubt that it happens, that you have this degradation and there is no doubt that in principle, surface enhancement leads to some complications. But I will not -- or to my opinion, to my knowledge, it is not like this

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that the risk is so high that you have to stop any use of polypropylene in the moment in all devices for all purposes. And that is what I expressed clearly at my presentations as well. It is a concern and to my opinion, there is no doubt that this happens, but it is not enough to forbid the use of polypropylene in medicine in the moment. But maybe it happen. It changes.

Q. What should FEG do about this knowledge and its surgeons and its patients that receive this mesh?

A. I don't have any specific information what they are doing as a consequence of this. To my knowledge, the way was to use only PVDF.

Q. Okay. But is it fair to understand that based upon your knowledge of the information available to you at this time, you're unable to determine the extent to which there is any clinical significance to any surface cracking that may be on this polypropylene mesh manufactured by FEG; is that fair?

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MR. ANDERSON: Objection to form.

THE WITNESS: As I told before, I have no doubts that surface cracking and enhancement of surface leads to a higher risk for complications. That is a clear relationship, causal relationship, that is proven by all our experience and all of this work.

I cannot give you a figure what does this mean to have these materials, but this should be a starting point. If you decide -- and that is my consequence, if you decide to sell polypropylene further on in your devices, you should study it very, very carefully because this, of course, is not -- a nonlinear process. It happens -- it may happen that 20, 30 years after implantation in young patients that you may experience things you don't want to see there.

So it has to be studied there.

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QUESTIONS BY MR. THOMAS:
Q. Do you have any ideas as to what you would expect to see?
A. In the worst case for the patient, it can be a malignant transformation because you have 30 years of chronic inflammation. We know this from medicine in general. Chronic inflammation over 30 years may cause some malignant transformation, and, this was, of course, the severest complications for the patients, yeah.
Q. Polypropylene sutures have been used now for over 50 years, haven't they?
A. Yes.
Q. Are you aware of any reports in the literature about clinical issues associated with alleged surface cracking in polypropylene sutures?
A. When we're looking to the literature, the number of scientific investigations of tissue response to foreign body materials is very, very limited and mainly for the meshes with the huge amount of sutures, it would be a better material to be

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investigated these effects with meshes. It mainly started in 1994. So you don't have a knowledge of 50 years of extensive research in this field.
When you -- if you would asked me five years before whether do you know some cancer case in relationship to textiles, I would say, no, I don't know any report, but meanwhile it changed. Meanwhile we know some.
I don't want to say that we have to expect it in certain number of patients, but it is a concern, yes.
Q. Are you aware of any reports in the literature about clinical issues associated with alleged surface cracking in polypropylene sutures?
A. Polypropylene suture surface cracking, there has been reports. I guess La Roche was an investigation of polypropylene sutures in the eyes showing this cracking or degradation of this material. So there is some literature showing that indicating that you have this degradation.

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Q. My question is not whether you show the surface cracking. My question is whether there are clinical manifestations resulting from the alleged surface cracking?
A. I don't know any study that was able to differentiate whether it was a surface cracking, whether it was a surface of the material, whether it was the functional biocompatibility of the device, therefore.
Q. Last year when you testified, you testified that polypropylene mesh appropriately designed could be used in a mesh.
Do you recall that?
A. Yes.
MR. ANDERSON: Objection. Mischaracterizes his testimony.
Go ahead.
QUESTIONS BY MR. THOMAS:
Q. Do you still believe that?
Has your opinion changed?
A. No. Can you, please, because it depends on -- can you please repeat?
Q. Is polypropylene fiber still an

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appropriate material to be used in a mesh?
A. It depends from your meaning of appropriate. Is it a possible solution not being forbidden by laws? Yes.
Q. As --
MR. ANDERSON: Let him finish.
MR. THOMAS: I thought he was, I'm sorry.
MR. ANDERSON: He's still counting on his fingers.
THE WITNESS: When I would prefer the best material, I wouldn't choose polypropylene.
QUESTIONS BY MR. THOMAS:
Q. Is PVDF more expensive than polypropylene?
A. It's definitely more expensive, and it's more difficult to handle.
Q. And how much more expensive is it than polypropylene?
A. I don't know.
Q. When you say it's more difficult to handle, what do you mean?
A. What I was told by the textile

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engineers since over the past 15 years, you need a specific knowledge of how to make PVDF fibers because you need higher temperature to do so, you need specific equipment, you need other -- other spinning equipment to do so. Yeah. The advantage is that you can use a pure material.

Q. Dr. Klinge when a mesh is implanted, what bodily fluids surround the mesh.

A. Immediately when you place it there, depending on the skill of the surgeon, some blood. Usually some blood.

Q. Do proteins ultimately surround the mesh?

A. Yes, of course. There are some body liquids from the extra cellular liquids and they contain thousands, hundred thousands of proteins and due to the trauma, to the stress by the implant, you have a accumulation of liquid in this area. If you look very carefully to this area, you always find some accumulation of liquid around a textile implant.

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Q. Is it true that proteins surround the mesh fibers?

A. Our current thought is that the liquid containing the proteins, they are around the mesh fibers. The proteins themselves are too small. They just adhere to the surface, but they are not able to coat the entire filament to my --

Q. Okay. Do you know of any impact or effect that these fluids have on the characteristics of the mesh?

MR. ANDERSON: Are you talking polypropylene?

MR. THOMAS: Yes, polypropylene. Thank you.

THE WITNESS: It is necessary to think or to specify which characteristic of the mesh.

QUESTIONS BY MR. THOMAS:

Q. Have you ever heard of a term "plasticizer"?

A. Yes, but not in the context with meshes and proteins.

Q. That the bodily fluids as it

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gets to the mesh will make the mesh softer and more pliable?

A. I never realized this in the context with the -- with polypropylene or with meshes.

We used the pre-coating with vascular grafts. They were preclotted with some substances to change the appearance, but for textiles meshes made of polypropylene with a fiber of -- in a diameter of 120 microns, I cannot believe that any protein can change significantly the properties of this.

Q. Have you ever studied the extent to which bodily fluids soften meshes and make them more pliable?

A. No.

Q. When a mesh is explanted, the bodily fluids and proteins remain on the mesh, correct?

MR. ANDERSON: Objection.

THE WITNESS: When you explant a mesh, you usually have a block and you have a lot of scar tissue and

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somewhere in between there are these fibers. There is some liquids, some cells there, yeah.

QUESTIONS BY MR. THOMAS:

Q. And once you take the explant out, you place it into formalin?

A. Yes. Either you want to make some specific analysis. If you want to make an electron microscopy, you need some other solution for fixation, or if you want to make some genetic analysis, you have to freeze it down later on making some other -- so these are the three options you have usually.

Q. Okay. So you can freeze it, you can use formalin or --

A. Yeah.

Q. -- there's some other preparation you use for electron microscopy?

A. Yes.

Q. Tell me what that is.

A. For example, glutaraldehyde.

Q. I'm sorry?

A. Glutaraldehyde.

Q. I don't have any idea what you

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just said.
MR. ANDERSON: Glutaraldehyde. Or glutaraldehyde.
QUESTIONS BY MR. THOMAS:
Q. Okay. Under what circumstances have you used --
MR. ANDERSON: Glutaraldehyde.
QUESTIONS BY MR. THOMAS:
Q. -- glutaraldehyde in the preparation of samples for scanning electron microscopy?
A. There has been some time where we tried in some research projects to do some electron microscopy and, therefore, we had to make this specific fixation where we wanted to look to the collagen fibers. Collagen 3 has very small fibers. So when we were bound to make this fixation and we were asked to make this fixation with glutaraldehyde.
Q. Why did you use glutaraldehyde as opposed to formalin or formaldehyde, what was the reason?
A. Because we received a protocol from the guys making the electron microscopy

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and that we should use this. I'm not an expert to say the different possibilities to make a preparation for some investigation. I just told you what my experience was that we have some different options to make it.
Q. Okay. And how many occasions have you prepared slides for scanning electron microscopy where you've used glutaraldehyde?
A. How many slides for electron microscopy?
Q. Yes.
A. I don't recall. Most often I think it was to analyze the collagen, the quality of collagens. There we had -- over some years, we had projects where we made electron microscopy to look to the protein -- to the collagens.
Q. Have you prepared any samples for scanning electron microscopy in the last three years using glutaraldehyde?
A. Not that I recall.
Q. Have you prepared any samples using glutaraldehyde for scanning electron

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microscopy where you analyze the extent to which there were --
A. Degradation?
Q. -- surface cracking found on polypropylene?
A. Not that I recall.
Q. Doctor, on pages 40 to 42 of your report, you have three images that come from the report of Dr. Jordi; is that correct?
A. Yes.
Q. Did you select the images that were to be included in your report?
MR. ANDERSON: Objection as to whether or not there's work product and who selected what images.
QUESTIONS BY MR. THOMAS:
Q. Well, then I'll ask it this way.
Are Figures 13, 14 and 15 of any particular significance to you in your opinions other than just a representation of what was seen in images from Dr. Jordi?
A. I don't see any significant

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differences to many others so --
Q. Do Figures 13, 14 and 15, to your knowledge, have any relationship to Carolyn Lewis?
A. Yes. I know --
Q. I didn't see it in your report. That's why I'm asking.
A. I remember I received a lot of images from other devices, but from this device specifically as well. I guess it is from this case.
Q. How do you know that? You say I guess.
A. I have to be -- look careful every sentence there whether we have already written it here. Otherwise, if it's not written here, I have to check the files --
Q. Okay.
A. -- with the images there.
Q. I did not find it in your report where you identified these --
A. Sorry.
Q. -- images as being associated with a particular person. That's why I asked

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the question.
MR. ANDERSON: No, but he reviewed Jordi's report.
MR. THOMAS: I understand that. And Jordi has 22 mesh explants, too. I don't know which ones he picked.
MR. ANDERSON: Yeah, they're all identified by identifying number in Jordi's report. So if you want us to go get Jordi's report out and look through and identify which ones are Ms. Lewis, we can certainly take the time to do that. Or I can tell you which one it is or however you want to do it.
MR. THOMAS: I was going to ask -- I do want to see the report he has because the report he has is dated a different date than the report that you produced. The report that's identified in his report is dated October the 12th, 2013.
So do you have that with you, the one that he reviewed here?

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MR. ANDERSON: No, but it would be the exact same report as Jordi did.
MR. THOMAS: I don't -- it's 19 days before his deposition. You remember we had two marked there with different dates. I never did figure out --
MR. ANDERSON: Because we reprinted off the first page, and when we reprinted off the first page for you, we printed it as the same day as the depo.
QUESTIONS BY MR. THOMAS:
Q. As you sit here today, Doctor, do you know whether the Figures 13, 14 and 15 are from mesh explanted from Carolyn Lewis?
A. I'm not sure whether this is precisely from her, but they all look quite similar.
Q. Okay. You've told me before that you're not a chemist or an analytical chemist.
Have you studied the extent to which -- strike that.

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Have you studied how polypropylene degrades?
MR. ANDERSON: Objection. It was asked yesterday because you wanted to get into expert opinions yesterday. So we're going back over the same ground.
MR. THOMAS: Not really. I just didn't remember I asked the question.
MR. ANDERSON: You asked a lot of questions on degradation yesterday.
MR. THOMAS: Okay.
MR. ANDERSON: Because you asked to go ahead and start asking expert questions yesterday.
MR. THOMAS: Can we keep going so we can get out of here?
QUESTIONS BY MR. THOMAS:
Q. Can you answer the question?
MR. ANDERSON: Have you studied how polypropylene degrades? That's his question.
THE WITNESS: We have studying

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in the meaning that looking to the data, yes. Doing own studies, experimental studies looking to the chemistry, what happens there, no.
QUESTIONS BY MR. THOMAS:
Q. Do you defer to Dr. Jordi for that type of analysis?
A. Yes. Definitely.
Q. Doctor, let's go to page 76 of your report, please. Page 76 of your report deals with the heading "Alternative Design."
Is it your opinion that ULTRAPRO™ is an appropriate alternative design for the treatment of stress urinary incontinence in women?
A. No.
Q. Why?
A. Because the structural stability of ULTRAPRO™ is not sufficient to withstand -- or to preserve the big pores under -- under these conditions of biomechanics as it is required for the use as a sling.
Q. Is there any mesh design

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currently marketed by Ethicon that is an appropriate alternative design for the treatment of stress urinary incontinence?

A. I'm not aware of all products from Ethicon that are available in the moment. In this context, I cannot say whether there is already some device that I can consider sufficiently to be sufficient. It should have -- it has to be tested all these.

Q. And when you mean it has to be tested, what do you mean?

A. To find the optimum structure, the optimum -- the development -- for the development of the optimum structure, you need some studies to define this.

Q. Tell me what studies you need.

A. More or less you need studies to every point of concern that was mentioned in this report and this -- these studies to every point mentioned in this report should -- has to include a lot of preclinical studies in appropriate animal models, in appropriate functional testing, in

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appropriate textile characteristic and then you may get a good impression which design of this -- of your device you want to have is -- has the lowest risk.

Q. So first thing you mentioned preclinical studies.

Is that animal testing?

A. It can be in vitro testing. It can be animal testing.

Q. Do you need both?

A. Yes.

Q. And the in vitro testing is what?

A. In vitro testing is maybe it's the counting of particle loss after manufacturing. It can be the behavior in liquids, the degradation, the combination of these materials with some cells, what happens there, what is the overgrowth. A lot of questions can be addressed in this field.

Q. Okay. And do you need to do the in vitro and animal testing before you do the function testing?

A. Everything has to be in

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parallel. If you want to have a good schedule for how to do so, a good example of -- a good realization of this principle is what we have done with the VYPRO or the principles that we defined at that time, all of these studies, the 100 publications, all of this together gives a good impression or helps you to understand, to find a good device.

Q. And you began with the design of VYPRO in 1994?

A. 1994.

As I told you, December of 1993.

Q. And when was VYPRO launched?

A. 1998.

Q. Is it your opinion today that PVDF is the only appropriate polymer to be used in mesh for implantation in the treatment of stress urinary incontinence?

A. No, but, to my knowledge, it's the best we have.

Q. What other polymers are appropriate for use in a mesh for

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implantation in the treatment of stress urinary incontinence?

A. I cannot answer. This is a very general question. There are a lot of polymers, experimental. We're working on polymers and other polymers so there are a lot of other -- maybe a lot of other alternatives. There are some literature providing new materials but in the moment from my -- to my knowledge, PVDF has the best results.

Q. Okay.

A. But I cannot give you a complete list of all alternative -- possible alternatives.

Q. Can you give me a list of three possible alternatives?

A. I cannot give you a list of one alternative that is better than PVDF.

Q. And I know that.

What I asked you is there --

A. There are some polyimides, polyulitars. These are classes where you can try to look to see alternatives.

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Q. Is it your opinion today that polypropylene is not an appropriate mesh for implantation for the treatment of stress urinary incontinence?
A. I think some minutes ago I already said that the word "appropriate" is -- makes it impossible for me to say yes.
Q. Is it your opinion to a reasonable degree of scientific and medical certainty that the use of polypropylene in meshes for the treatment of stress urinary incontinence is unreasonably dangerous?
A. Unreasonable dangerous? Has to be seen in regard to the specific situation of the benefits and risks. If you use this implant of polypropylene in an 80-year-old patient, I will not expect that you will experience any problem just because of degradation within the next one year. So it --
Q. Do you have a --
A. I cannot give a general statement to this.
Q. Okay. Do you have an opinion

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to a reasonable degree of scientific and medical certainty whether it's appropriate to use polypropylene mesh in hernia repair?
A. The same objection as before, the term "appropriate."
Q. Do you have an opinion --
A. Makes it difficult or impossible for me.
Q. Do you have an opinion to a reasonable degree of scientific and medical certainty as to whether the use of polypropylene in hernia repair is unreasonably dangerous?
A. The -- my present opinion is that it is not so dangerous that it should be forbidden in today to have -- to use it and, therefore, I'm convinced that it is tolerable or acceptable to use polypropylene in medicine.
Q. Okay.
A. But if I may, it depends on the structure.
Q. Right.
A. So it's not a general free

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comment on polypropylene in general.
Q. I understand that.
And, Doctor, you have to start somewhere and choosing the textile is a pretty fundamental issue for any mesh that you might use, you agree with that?
MR. ANDERSON: You mean the polymer?
MR. THOMAS: Yeah, that's what I meant.
QUESTIONS BY MR. THOMAS:
Q. Doctor, you have to start somewhere and choosing the appropriate polymer is an important first step in the design of any mesh, would you agree with that?
A. Yeah. I would agree that this is a first step because then it leads you to further decisions.
Q. And even a PVDF polymer can be designed in a way that's unreasonably dangerous, do you agree?
A. Definitely, yeah.
Q. And so as I understand your

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position for use in medicine today, either PVDF or polypropylene are appropriate -- or excuse me, are not unreasonably dangerous if designed correctly?
A. Again, there is this inappropriate. It depends on what you're looking. You can create some acceptable textile structures of both, of polypropylene and PVDF. You will find some different risks if you compare these two.
Q. Doctor, what is Exhibit A to your report? That's it right there. Those images.
A. These images?
MR. ANDERSON: That's Exhibit A?
MR. THOMAS: I think.
MR. ANDERSON: A was his CV.
MR. THOMAS: I am sorry, then Exhibit C. I apologize.
QUESTIONS BY MR. THOMAS:
Q. What is Exhibit C to your -- let me start over again so I get a good question and you give me a good answer.

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Doctor, what is Exhibit C to Exhibit 11?
A. Exhibit C is a collection of images I made from histological sections I received, and I received HE stainings and stainings with S100.
Q. Okay. Now, did you create the images that are in Exhibit C?
A. Yes, myself.
Q. And what did you receive -- strike that.
I take it you received certain materials from Mr. Anderson that allowed you to make these images, correct?
A. I received complete stainings in a box, each explant were prepared with the three stainings, three sections.
Q. So by the time you received them, the slides had already been stained?
A. Yes.
Q. And what stainings were done?
A. HE, this is this one with the red color, and there is an additional staining with a specific antibody S100 that

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marks nerves or nerval structures. This is a link to a brown color so in these you have this brown color where the S100 is positive.
Q. Okay. Is the HE two different stains or just one?
A. No, it's two.
Q. Okay.
A. Two.
Q. So you have one -- two --
A. No, it is two colors that are brought to one section. So it's a counter staining.
Q. You told me, I thought, that you had three slides?
MR. ANDERSON: Three of each.
THE WITNESS: Three of each. Three HE from patient or from case one, and three S100 from case one.
QUESTIONS BY MR. THOMAS:
Q. I see.
So you have six slides for each patient?
A. Yes.
Q. So you have 66 -- no, you have

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132 slides?
A. You're right. I'm not a mathematical expert. It's a big number.
Q. Do you know who prepared the slides?
A. Professor Kreutzer. I received a note that he prepared this with some numbers so that I can check whether the number of this data sheet was the same as on the slide, on the --
Q. Did you have any interaction with Dr. Kreutzer about how to prepare these slides?
A. Not directly.
Q. Did you provide information to anybody to give to Dr. Kreutzer about how to prepare these slides?
MR. ANDERSON: Other than conversations with me?
QUESTIONS BY MR. THOMAS:
Q. Let me ask it this way.
Doctor, do you know how Dr. Kreutzer prepared these slides?
MR. ANDERSON: Objection to

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form.
Go ahead.
THE WITNESS: I don't know in detail, but this staining HE is a normal procedure for every pathological department and the doing of S100 staining is a -- it's a standard procedure. Maybe I can use the word "standard" in this context. It is published in all of the reports where we presented these data. It is no specific knowledge to do these two.
QUESTIONS BY MR. THOMAS:
Q. What's Dr. Kreutzer's training, if you know? I've forgotten.
A. He's pathologist.
Q. That's what I thought.
And he's in Connecticut.
Have you ever met him?
A. No.
Q. Spoken to him?
A. No.
Q. Did you have any communication with Dr. Kreutzer at all about the slides

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that he presented to you?
A. No.
Q. Have you ever seen any written analysis by Dr. Kreutzer of the images that are attached as Exhibit C to your report?
A. No.
Q. Tell me again what an HE slide is.
A. HE slide is a staining of cells and of extra cellular matrix, mainly of collagen. So you have a blue color for the nucleus of the cells to identify the cells and you have a red staining mainly for the collagen and, yeah.
Q. Let's go to the very first slide that you have, very first image that you have on Exhibit C.
And down in the lower right there is a scale of 500 microns, correct?
A. Yes.
Q. And what's the magnification of this, do you know?
A. I don't know in this, but when I made the image there, I was asked -- I

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usually took the 40 magnification, 100, 200, 400. These are the options at the microscope. And then the analyzing system asked me which magnification was done there and then they put into the slide this scaling there.
So to place the scaling there, I had to answer the correct magnification. There are only four or five. So we have a look through the different things, then, of course, we will see whether it's the 400 or the 40.
Q. Well, there are different -- I see different scales throughout these photographs.
A. It's 40, 100, 200, 400 magnification.
So as I recall, these are the four different magnifications and there will be correspondingly four different scales here.
Q. Okay. What does this tell you about this first image in Exhibit C with -- lower right-hand corner it says 500 microns.

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In the middle of the first image on Exhibit C, there's a measurement of 168.53 microns.
Can you tell from looking at this image what the magnification is?
A. The magnification would be 40 or 100.
Q. Okay. Now --
A. When I saved the images, I name it so usually I get it from the name.
Q. I believe that one doesn't have any scale on it at all.
A. Yeah, sometimes I forgot it. Sorry. So 200 -- no, 500, 50, this is the highest magnification. This is 400, then this is 40. 40. 40 fold magnification.
Q. And how did you conclude that?
A. Because I've seen there one with the highest magnification and this was 400. And so in this the scale was only 50 and here we have 500 so it is one-tenth.
Q. Now, you made these images yourself from a scanning electron microscope?
A. No, from a conventional light

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microscope.
Q. And where did you have that light microscope?
A. In our lab on the third level in room 45 at -- no, ward 45, room 1. On a desk, we have two of them and on the left, there is a camera on it to make these images.
Q. Thank you, Doctor.
The first image to Exhibit C, I believe you said the red area depicts collagen.
A. It's mainly collagen, yeah.
Q. And what does the tan area represent?
A. The tan?
Q. This area over here, I call tan.
A. Here?
Q. Yes.
What is that?
A. There is nothing. No cells there.
Q. Does that mean there's no tissue?

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A. No tissue on this.
Q. Does that mean the slide does not contain any tissue as you're looking at it?
A. Yes.
Q. Okay. Does that mean that the area marked as 168.53 is at the right extreme of the sample you're analyzing?
A. In this picture, yes.
Q. And what is the area marked as 168.53?
A. This is a fragment of the polymer fibers. When looking to the slides, the first thing I try to do is to measure the diameter of these fragments so I know that there is a -- the cutting of these fragments is not directly horizontal to the course of the fibers.
But to have a rough impression what is a diameter of the fiber that it is in the area that I expect to be there.
Q. Doctor --
A. So that is around 150 microns.
Q. Okay. Now, do you believe that

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this -- is this a mesh fiber, is that what you're saying?
A. It is consistent with the -- with the fact that the -- that this fiber has the diameter of 160. If I would have seen a polymer with only 4 microns from this, then I would have some doubts that it's the right material.
But this finding is consistent with a polypropylene fiber of a TVT®-O or TVT®.
Q. So what does this mean to you?
What's the significance of this finding on this slide which is the first slide of Exhibit 3 to your report?
A. It's consistent with the assumption that it's a TVT®-O or a TVT®. If it would have been 250 or 300 microns, then I should to rethink about it. It's just a confirmation that I really just got what was written in the table.
Q. And so you're consulting a table as you review these images; is that correct?

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A. I have the information of this table, yeah, but usually I look to the images and without any knowledge so in a blind fashion.
Q. I understand.
Did you prepare the table which is prepared as the last page of your report?
MR. ANDERSON: I prepared it in accordance with the chain of custody forms.
MR. THOMAS: Did you prepare all of it?
MR. ANDERSON: Well, I had to get his ID number and the Jordi ID number and the Steelgate specimen number and all of the information that Steelgate had in conjunction with the various other information so that I could assimilate his -- the information that he provided on his ID number, and then everything from N to R he prepared or gave the information.
So the reason for doing this was to make it A, easier to keep up

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with the chain of custody so that you could see where it went from explant to his hands. It would also be consistent with the chain of custody forms that Mr. Snell and I agreed to and so it would make it easier at this deposition for you if you wanted to look at a particular device or whatever and be able to compare them.
So that was the effort that I put forth in order to try to put the information of all of the slides in one spot for both you and I.
QUESTIONS BY MR. THOMAS:
Q. And the identifier for these slides is in the lower left-hand corner; is that correct?
A. That is the number or the coating that I found on the slide, on the stainings, yeah.
Q. Was this number already on the staining or did you have to add it to this document?
A. No. I used -- I used -- I used

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the number from the stainings from Professor Kreutzer and then I placed them or I named the images according to this number and added the sort of staining and added the magnification in the name of the slides.

Q. Did you receive all -- did you see -- is 22 slides all you received or did you receive any more than that? Excuse me, strike that.

Did you receive slides from 22 separate patients, or did you receive more than that?

A. No, 21, 22 cases, different cases.

MR. THOMAS: Can we take a break a second, please?

MR. ANDERSON: Sure.

(Off the record at 2:42 p.m.)

QUESTIONS BY MR. THOMAS:

Q. Doctor, looking again at the first image of Exhibit C to your report, what of significance do you find in this image related to adverse reaction to mesh?

A. Just to explain I looked

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through all of these stainings there and I define some parameters which I've been looking at and these I put in this table and then I made some exemplary images of every case. It's even at this low magnification, it is just one small part of the section. The section is much bigger, and, therefore, I just want to cover the general impression of any of these findings that are on the table by these images.

So what you see here is appearance of a polymer fiber in a size that we expected. You see some fat tissue there at the lower part and you see extensive tissue here very close to this fiber. And this is indicated by the red color. This is the content of this image.

Q. Is fat tissue and collagen the same thing?

A. No. The fat tissue is this lower part by the fixation, by the staining. Essentially the fatty liquids are removed so you have almost empty spaces there and you can identify fat cells that you only have the

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cell wall around, and in these cells, the nucleus is at the bottom and you have an area in the middle where the fatty acids have been and, therefore, it is bright. You don't see significant structures in the fat tissue.

Q. Okay. So you showed me the fat tissue and the collagen and you've also shown me the polymer fiber.

What else is of significance in the first slide of Exhibit C?

MR. ANDERSON: Objection to the form of the question.

THE WITNESS: I wouldn't point out any others.

QUESTIONS BY MR. THOMAS:

Q. Okay. When you looked at the 22 different patients you said that you developed some parameters.

What does that mean?

A. The parameters I want -- in general, this -- looking at these samples I want to get a confirmation that what we have seen in all these animal slides, what we have seen in the human explants from the abdominal

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wall that this is confirmed by explants provided by Professor Kreutzer, as well and, therefore, the first is that I look to the fiber size, I try to measure it, that I really am sure that it's a monofilament -- a monofilament in a size that has to be expected there, that was the first.

The second is the bridging, whether I see pores, the room between two filaments that are filled with fat and I made a coating to get or to differentiate whether these pores are frequently seen, rarely seen, always seen or never seen.

The next was whether there was some sign of folding on shrinkage. The main structure should be -- if there is no folding and shrinkage, should be in a plain way detectable in these stainings or shouldn't be in a folded or in a wave-like position.

If I saw somewhere at the mesh that there is a doubling of the structures or there is a configuration that cannot be explained by a plain positioning, then I marked it with a yes.

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And then finally I looked at the S100 stainings, whether there are some nerves in the -- within the scar area of surrounding the mesh because in former times, there has been the discussion the big nerves are not in this area, therefore, it is impossible that the mesh interacts with some nerves and for this purpose, I just mentioned whether there are some nerves, yes or not, and in fact, you see nerves in this -- small nerves that cannot be visualized by the surgeon during the operation, but you have there some nerve structures very close to this wound.

These are the four points and every slide I analyzed to get an opinion on these four things, for every case.

Q. The parameters that you've just described, are those parameters unique to this case?

A. Yes, unique.

Q. Okay. And why did you pick those parameters?

A. Because the value of this -- of

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these explants is that they allow me to confirm that -- or to test whether what we have seen in the animal tissues, in the human tissues of the abdominal wall, whether this is true for these. I had the data from Professor Klosterhalfen from his explants and it already indicated that it is similar or comparable and now I personally have the option to test -- to have it tested at these 22 sections.

Yeah, overall, in fact, you see this extended bridging there, you see that the distance between the fibers is less than these 1,400 microns. So it is -- it underlines, again, that it is irrelevant to discuss these 1,400 because if you look to the tissues, you see this bridging with these devices.

Q. Okay. You said a number of things in your answer I want to talk about.

You mentioned you received some explants from Professor Kreutzer; is that right?

MR. ANDERSON: Objection.

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Slides.

THE WITNESS: Slides.

The data explants from Professor Klosterhalfen.

QUESTIONS BY MR. THOMAS:

Q. That's better. I thought he said explants. That's -- so the only thing you received from Dr. Kreutzer were the slides?

A. Yes.

Q. Now, the information that you received from Dr. Klosterhalfen was the data that he generated from his analysis of his explant collection, correct?

A. No, I got his data and I had the opportunity to have a look at some stainings in Düren as well.

Q. Okay.

A. So I've seen it.

Q. But just so I understand, the stainings that you looked at in Düren were stainings that Dr. Klosterhalfen had already prepared and analyzed; is that true?

A. Yes.

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Q. And reported on his findings for those stainings?

A. Yes, but in the moment, I didn't know it. He just placed these tissues to me and so, yeah.

Q. Okay.

A. I could not relate it to the databases. It was -- again, it was one way to test whether this was confirmed in these tissues with these explants what we -- what our points of concern are.

Q. What form did the information take that Professor Klosterhalfen gave to you, the data that you talked about?

Is it a chart or is it information on the -- that contains his information -- strike that.

Did Professor Klosterhalfen give to you a document that detailed his analytical findings from his explant collection?

A. I had an Excel sheet where he had some of his findings.

Q. Is this the Excel sheet we

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talked about last year, the same sort of thing that you have on your computer?
A. Similar. Similar.
Q. Is it the same document, just more explants?
A. No. No. We talked last year about only explants, full explants, of the abdominal wall.
Q. Okay.
A. Now it is in other Excel sheet for the explants from the pelvic floor.
Q. Okay. And did you analyze the data provided to you by Professor Klosterhalfen to understand the complications which occur from mesh implants in a pelvic floor?
A. I made an analysis of this data in regard -- or to see whether these data confirm our opinions and our experience from the abdominal call.
Q. In addition to the Excel spreadsheet that you have of Professor Klosterhalfen's findings, you also went over to Düren and looked at some slides, correct?

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A. Yes.
Q. Did you look at all of the slides that he had?
A. No.
Q. How many did you look at?
A. About 20 to 30.
Q. Why did you look at 20 to 30 slides?
A. To have it seen by my personal eyes.
Q. Okay. Have you produced to us the Excel spreadsheet with the data that you received from Professor Klosterhalfen?
A. Not that I recall.
MR. ANDERSON: You have it. It was the one that we produced to you right before Klosterhalfen's depo and that was the one that Henry also gave to you at the depo or showed you at the depo.
MR. THOMAS: That's the Klosterhalfen exhibit from the BARD litigation.
MR. ANDERSON: Correct. That

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correlates to the 473, I forget the number, pelvic floor explants in Düren that he's referencing now.
QUESTIONS BY MR. THOMAS:
Q. Okay. And you were relying on the data generated by Professor Klosterhalfen in part for your opinions that you're giving from your review of these slides; is that fair?
A. There is no -- I don't understand whether you see a relation to this. We have our experience that bridging is important and so on, and we have tested by our own explants. I took the opportunity to have it controlled in Düren. I took the opportunity to have it tested by the data sheet of his and then I took the opportunity to have it tested -- test our opinions, our experience at the 21 cases that I got from Professor Kreutzer and finally eventually I took the opportunity to check this at the last 22nd of this case.
So it is subsequently permanent confirm -- or looking for a confirmation or a

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rejection of what we know.
Q. And just so I understand, this is the collection of explants maintained by Professor Klosterhalfen in Düren that I'm not allowed to see; is that true?
MR. ANDERSON: Objection to form.
MR. THOMAS: It's true, isn't it?
QUESTIONS BY MR. THOMAS:
Q. This is the collection protected by German privacy laws that limits and prohibits me from looking at it without permission from the patient.
Do you know the answer to that?
A. I have read it, but I'm not familiar --
Q. I'm talking about whether I can see it.
A. What?
I'm not an expert what are the legal steps to go over there and to do so. I read it in the depo form.
Q. Now, when you were at the

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university, you were a surgeon and you practiced as a surgeon until 2006, correct?
A. I am a surgeon and practiced until 2006.
Q. You did not work for the Institute of Pathology?
A. No.
Q. And that was Dr. Klosterhalfen who worked in the Institute of Pathology and collaborated with you on your work?
A. Yes.
Q. Are you permitted at the hospital where you work to sign pathology reports?
A. No, I'm not permitted to do.
Q. Did you have a residency in pathology?
A. No.
Q. Did you have a fellowship in pathology?
A. No.
Q. Have you ever been an editor or reviewer of a pathology journal?
A. No.

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Q. Are you familiar with the staining technique known as neurofilament staining?
A. I've read it and I know that it exists.
Q. Have you ever used neurofilament staining?
A. Not that I recall in the recent time.
Q. What is the purpose of neurofilament staining?
A. It's another option to visualize nerval structures. More specific.
Q. More specific.
It can -- okay. Did you ask for neurofilament staining of the samples that you looked at?
A. No.
Q. Why not?
A. I didn't ask.
Q. Why not?
A. Because in our experience, we made at -- or we preferred due to the advice of Professor Klosterhalfen the S100 staining

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to get an impression whether there are some nerves or not. And we're not -- or the main focus of our research was not to specify there whether it's neurofilaments or there are so many different options to use antibodies against nerves so we selected S100.
Q. Okay. You and Dr. Klosterhalfen decided which staining method to use?
A. Mainly he decided. I think we started at the -- in the '90s and he proposed to use S100 because this was established in the Institute for Pathology and we got good images and good information from this and, therefore, it is still widely used and we are satisfied with it.
Q. Doctor, isn't it true that normal vaginal tissue contains nerve fibers?
A. Yes.
Q. And so the fact that your staining picks up nerve fibers is not remarkable by itself?
A. As I told you, the intention to

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look for these fibers has been discussions we had that someone is standing up and said, okay, it cannot be that someone -- some patient has some pain because the big nerves we took care during the operation and the big nerves are far away and that just to demonstrate to an audience that there are these tiny nerves that cannot be seen by any surgeon when he's in this field, we just made it for this purpose and, therefore, we didn't make any further analysis. Just yes, no, and as you said earlier, everyone knows that these nerves are there, but some of my colleagues they don't want to know it maybe.
Q. What do you mean, "They don't want to know it"? I don't understand.
A. They ignore this fact sometimes in discussions.
Q. They ignore the presence of nerves?
A. Of these small, tiny nerves there, yeah.
Q. I see.
(Klinge Exhibit 24 marked for

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identification.)
QUESTIONS BY MR. THOMAS:
Q. Doctor, I've handed you what's been marked as Deposition Exhibit Number 24 and ask you if that's the pathology report for Carolyn Lewis?
A. Yes.
Q. Thank you. I'm sorry, I didn't hear your answer, I apologize.
A. I didn't get the question.
MR. ANDERSON: He didn't answer. He was still looking.
QUESTIONS BY MR. THOMAS:
Q. Oh, okay.
Did the pathology report inform your opinions at all about the tissue reaction Ms. Lewis had to the mesh implant?
A. I didn't get the -- did the pathology -- no, first of all, I looked afterwards to this pathology report, and as I tried to explain, I'm looking to bridging, folding, nerve contact and this is not included here. But what they describe is the usual appearance and, unfortunately, it's a

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usual report given by pathology when they get an implant, but they never looked to the pores or the extent of the scar tissue.
So I would expect a similar report in Germany.
Q. And just to be clear, there's nothing remarkable in Exhibit 4 which is the pathology report to Ms. Lewis that the pathologist found after the explantation to suggest any remarkable tissue reaction with the mesh; is that true?
A. It is too unspecific. It just confirms that the routine pathology is not able to give a detailed description of the tissue reaction to a device.
Q. Now, are you able to detect fibroblasts as you look at these images?
A. Yes, yes, you can see them.
Q. Are you able to detect microcapillary cells?
A. Microcapillary, endothelial, yes, you can see it.
Q. What is a microcapillary cell?
A. I assume that you are thinking

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of some endothelial cells forming vessels.
Q. And what are fibroblasts?
A. Fibroblasts are cells that are used to -- mainly their task is make a deposition of collagen there. They are very -- or if you have an injury or a damage in the tissue, usually the fibroblasts are called to make an unspecific repair by forming scar tissue in this field of damage and defect. It's -- they are the cells mainly responsible for the scar tissue and has to be differentiated from more specialized cells as fat tissue, for example.
Q. And what is -- what are -- what's collagen?
A. Collagen is a protein. There are 13, 16 different collagens. Mainly we have to deal with collagen 1. That is a protein of several helixes and this is responsible for the stability of fascia and of skin. It has to be separated from collagen type 3. That is a collagen that appears usually at the early days of wound healing and later on is replaced by this

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stable collagen 1. An increased amount of collagen 3 is an indicator of an impaired wound healing and indicator for high risk for recurrent hernia.
Q. Is the presence of fibroblasts, microcapillary cells and collagen bundles inconsistent with the formation of scar plate?
A. Complete different things. They are -- they contribute to the extent of a scar.
Q. But the presence of --
MR. ANDERSON: Were you through with your answer?
THE WITNESS: What?
MR. ANDERSON: Were you through with your answer?
THE WITNESS: Yes.
QUESTIONS BY MR. THOMAS:
Q. But the presence of fibroblasts, microcapillary vessels and collagen bundles are an indication of proper tissue integration, correct?
A. You can't decide from the

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presence of these cells either whether it's a scar plate or a scar net. If you stick to these words or whether it's proper or whether it's inadequate, it's just described that there is some scar reaction there, but it gives -- it doesn't give you any hint whether it's sufficient, necessary or too much scar.

Q. Have you read the expert report of Dr. Zing?

A. Yes.

Q. Okay. And do you agree with the findings of Dr. Zing?

MR. ANDERSON: Well, objection. Which ones? It's a long report.

Which ones?

QUESTIONS BY MR. THOMAS:

Q. Just generally, do you agree with the findings of Dr. Zing?

A. I need to go to the paper otherwise.

Q. Do you have a recollection of anything in the report that you disagreed with?

MR. ANDERSON: Again,

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objection.

MR. THOMAS: I understand.

MR. ANDERSON: Without letting him see the report.

THE WITNESS: My rough recollection was that he described a lot of things that I can agree to, but my impression was that he didn't have a -- or that his experience in comparing tissue reaction to different textile structures, that this -- his experience is limited.

QUESTIONS BY MR. THOMAS:

Q. Okay.

A. And that his statements whether it is a -- about the quantity in comparison to others, that there are only very few remarks on it. But otherwise we have to go to --

Q. Okay. Let's go to page 70 of your report.

Now, are the images of page 70 of your report also contained in appendix C?

A. I'm not sure. I made a lot of

Page 572

images, but I have to look whether all of these are here or --

MR. THOMAS: Do you know, Ben? I don't want to spend my time looking through the report and I'm just curious. I'll want copies of the -- I will want copies of these if they're not the same.

MR. ANDERSON: I don't know if all of them are the same, but certainly have an agreement with Burt that we can -- that we need to swap slides. Zing's come to me, mine go to you.

MR. THOMAS: Okay. I didn't know that.

MR. ANDERSON: Yeah, you-all need to talk more.

Yeah, so you'll have the opportunity to -- or have your guy look at ours and I need your guy -- I need yours, too. We just need to get that worked out.

MR. THOMAS: You need the

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slides --

MR. ANDERSON: The slides.

MR. THOMAS: -- somebody else has. They're not mine.

MR. ANDERSON: So they can be observed by someone else that are not yours.

So I can't really answer this question.

MR. THOMAS: Okay. We'll just make a record of that fact. We're not sure that the images that appear on pages 70, 71, 72 and 73 and 74 also appear in the appendix C.

Mr. Anderson advises that there's an arrangement whereby we will exchange slides so that Dr. Zing will have an opportunity to review what Dr. Klinge's reviewed, and Dr. Klinge will have an opportunity to review what Dr. Zing reviewed; is that correct?

MR. ANDERSON: That's correct. I know without every one of these

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photos and taking up your time, without comparing all of these, I know that some of them are certainly in the back.

MR. THOMAS: And probably by definition since there are so many of them, some of them aren't.

MR. ANDERSON: I don't know if that's true.

QUESTIONS BY MR. THOMAS:

Q. So going to page 70, do you know if the images from page 70 are from Carolyn Lewis? And the reason why I ask is on the next page, you refer to her by code name on page 71 for the first time.

A. Yes. And, therefore, the first images are not from this case. These are from the first 21 cases. And then later on, one week later, I got the case BAL 13-23 and, therefore, the first images are not from her.

MR. ANDERSON: It's BAL 13-23.

QUESTIONS BY MR. THOMAS:

Q. Why didn't you say Carolyn Lewis in your report?

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MR. ANDERSON: Objection.

THE WITNESS: No specific reason for it.

QUESTIONS BY MR. THOMAS:

Q. Okay.

A. When I got all this -- all these numbers, I have no problems to use these numbers. If I take numbers of -- names here, I'm not allowed -- I'm not well-informed about possible consequences there. But when I get a slide with a code, I take the code.

Q. Dr. Klinge, so the first images that relate to Carolyn Lewis appear on page 71?

A. Yeah.

Q. Now, what are the three images that appear in the middle of page 71?

A. All these are HE stainings and should give you an impression that it's only a small part of the tissue there. It's not a big section that has been stained there. And a lot of red there, a lot of deposition of collagen and I used a polarization filter.

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It has been possible to detect polymer particles better because they start to get bright there in this.

Q. Let's stay with the three images on page 71 for right now.

As you look at the three images on page 71 --

A. Yeah.

Q. -- is there anything about those images that suggests to you that there is inadequate tissue integration -- strike that.

Looking at the images on page 71, the three right there in a row, is there anything about those three images that suggests to you that there's an inappropriate inflammatory response to the mesh?

MR. ANDERSON: Objection to the form.

Go ahead.

THE WITNESS: What you see in this is in the middle part, it's a higher magnification than you see some inflammatory infiltrate close to the

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polymer that is the typical foreign body reaction.

QUESTIONS BY MR. THOMAS:

Q. I am sorry, that's a typical foreign body reaction?

A. Yeah.

Q. Okay. Thank you.

A. Foreign body reaction.

On the right side, you see that there are some fibers, and in between, the space is completely filled by scar tissue and on the left side, you see the lowest magnification, then you see, again, that there nowhere is a huge area of fat tissue, but all is a scar tissue there.

So overall, this HE staining confirms that this mesh material completely is integrated in a scar field.

Q. Okay. We talked earlier about a scar net or a scar plate?

A. Yeah.

Q. Is it a scar net or a scar plate?

A. It is obviously a scar plate

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because a scar net would require some fatty tissue in between the filaments. And if you're measuring or looking at the distances between the filaments, the filament is 150 microns and the distance is very close together. So you can suspect that this is at the linking part and not in the middle of the pores, but if you look through the entire section, you always find images like here, not the big distances.

Q. Okay. And when you get these slides, has the mesh -- does the mesh typically fall out of the slides before you analyze them?

A. Usually, it is a very thin section there and by the knives, it take the polymer fibers out and usually they are -- they are out and you only see the cells around.

Q. Okay. So you actually when you look at the slides, you're looking at a hole as opposed to the polymer?

A. Very often, yeah.

Q. Can you tell on 71 whether

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you're looking at the polymer or the hole?

A. From these images, it is very small, but I think even if you make it bigger, that you don't see directly the polymer in this, but only the holes.

Q. Okay. The middle slide depicts a normal fiber foreign body reaction, correct?

A. A typical.

Q. A typical foreign body reaction.

Is there anything else remarkable about the middle slide?

A. No.

Q. Now, the slide on the left, you said the red, does that depict collagen?

A. Yeah. Mainly collagen and this is expressing the scar reaction there.

Q. Okay.

A. It's not the yellow color of the fat tissue, but it's the red color of collagen-rich scar. Fibrotic. Fibroconnective tissue.

Q. So I thought collagen was good.

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MR. ANDERSON: Objection.

THE WITNESS: In sweeties, it's perfect. There's some sweets made of collagen. There, it's great.

QUESTIONS BY MR. THOMAS:

Q. I thought collagen deposition between pores was a good thing.

Is that not true?

A. It depends if you have a wound from a burn, then you get an extensive scar formation, and I don't know whether you have seen these images of contractures for these patients. It is a catastrophe. So scar is defect healing, but scar is part of the physiological wound repair as well. It depends on the quality and quantity of the scar.

QUESTIONS BY MR. THOMAS:

Q. Describe for me, please, in as detail as you can, what it is about the picture on the left on page 71 that shows you that this is a scar plate?

A. There is no -- not any or there is no area where I can identify a pore that

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is filled by fat tissue. That is not filled by scar and our definition of bridging was that the pore is completely filled by scar tissue.

Q. When you say "your definition," that definition accepted generally in the field of pathology?

A. That is the definition that we published since years what I -- what is accepted by the documents from Ethicon I saw, I never realized that there was any objection to this.

Q. My question is: Do you know that the definition that you used is acceptable in the field of pathology?

MR. ANDERSON: Objection.

THE WITNESS: I don't know what is your feeling, what does it mean acceptance in the field of pathology, by whom, in what specific situation?

QUESTIONS BY MR. THOMAS:

Q. Okay. Let's go to the same page on the right side, I would like for you to describe for me, please, what is

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remarkable about the image on the right side of the three section on page 71?
A. This is a section where you see in the middle the two almost circular holes where it is likely that there -- a polymer fiber has been there. You see on the left side of this image that it's a little bit not circular because you have a diagonal cutting in this area.
On the right-hand side, you may have the impression that there may have been some of the polymer fibers, but it's not clear whether it's a destruction of the tissue there by the cutting process, but, however, all of the tissue in between the fibers it is scar.
Q. Next page, page 72 at the top, there are three images there and the heading says, "Some areas of the polymer showed considerable M homogeneity of the crystal structure that can hint to a present change of the crystal structure."
What does that mean?
A. As I told you, we have -- we're

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frequently using this polarization filter because this allows us to differentiate between collagen 1 and collagen 3 or to -- yeah. And to identify collagens better.
And another option of this polarization filter is the identification of some smaller particles, and I use this to look whether there are some particles. And if you're looking at the upper row in the right picture, you see that there are very, very small particles there, highlighted there. And it is usually just doing it without the filter, you will not see them because they are almost the same appearance as some cells. But when using the filter, you really see in a there is a foreign body.
On the left, you see a polymer fiber as I would have expected it, homogenously as a polymer. In the middle, you see that it is different. I have no explanation for this. The only explanation I can imagine is that there is some heterogeneity or change in the crystal structure that leads to this different

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rejection of the light there.
It is just a -- what I have seen there, I didn't know any literature making deeper studies to relate degradation to this, but I think it is a finding that may offer the option to make investigations using this filter when you want to look at the degradation of polypropylene.
Q. Do you have an opinion to a reasonable degree of scientific certainty that the image in the middle of the three-image set on page 72 is degradation?
A. As I tried to explain, there is no other information about the -- or confirmation that degradation can be seen by this but for my -- from my point of view, it is consistent with the opinion that there is some structural change, but I need further confirmation by further ongoing studies to prove this, but I just want to mention this.
Q. Okay. So just so I'm clear and I can stop asking questions about it, is it fair that you do not have an opinion to a reasonable degree of scientific certainty

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that the image in the middle of those three is degradation of the polypropylene mesh?
A. Yes.
Q. Okay. Is the image in the middle of the page of 72, is that your camera? What is that?
A. The middle here?
Q. Yes.
A. No, it's another image of this section where you see the different appearance of the polypropylene.
Q. I am sorry.
A. Down there is a polymer which seems to be intact as I would have expected it, and in the middle, you see some light changes of the appearance where I don't have any detailed explanation for the studies. It's a new finding.
Q. These samples came to you fixed in formalin, correct?
A. Yes.
Q. And slides were created.
Do you have any idea of the extent to which the creation of the slides

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could create any kinds of particles?
A. No. It's -- yes, of course, it has to be -- or the type of fixation, the type of handling can -- or can make some particles.
So, therefore, in the upper row, where you see on the left side some very small particles there, I cannot be sure whether this is done by the cutting, by the preparation of these sections for these stainings or whether it has been other reasons.
But if you're looking to the lower part of this, where you see a big particle, a fragment of the fiber, there you see that you already have some surrounding tissue response there and, therefore, it is clear that this particle has been implanted during the index operation there.
Q. Okay. Have you finished your comments and remarks about the top four images?
A. Yes.
Q. Moving now to the image that

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you just discussed, the single image at the bottom of page 72, and it says, "Around the separate particle, the usual tissue reaction can be seen is known from the tissue reaction to polymer fibers."
Do you have an opinion to a reasonable degree of scientific certainty that this was a particle in Mrs. Lewis that came out with her tissue explant?
MR. ANDERSON: Objection to form.
THE WITNESS: I've seen this in the sections which I got and saw this particle in these slides there.
QUESTIONS BY MR. THOMAS:
Q. Okay. Do you have an opinion as to whether this particle was -- strike that.
Do you have an opinion as to whether this image on page 72 is actually a part of the polymer that was cut?
MR. ANDERSON: Objection.
THE WITNESS: The polymer always is cut when you make this

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section, but in contrast to the particles on the -- in the upper row, you see that there is a reaction of cells around, which is very tied together to the surface of this particle and this needs time. So it is impossible that this particle is the result of the section and it shows clearly that even these particles have the typical foreign body reaction with the foreign body giant cells and the inflammatory infiltrate there.
QUESTIONS BY MR. THOMAS:
Q. What is your opinion with respect to the specific particle?
MR. ANDERSON: Other than what he just said?
MR. THOMAS: Right.
MR. ANDERSON: Okay. In addition to what you just said.
QUESTIONS BY MR. THOMAS:
Q. Any further comments that you have about this specific particle?
A. No.

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Q. Can you tell by looking at the -- what you've described as a particle on page 72 -- strike that.
Let's go to the next page.
Wait a minute. Before we do that, the tissue reaction to the polymer on page 72, "Consists of an interzone of polymorphous mononuclear inflammatory cells with some confluent foreign body giant cells as a sign of chronic inflammation, mainly located at the interface the polymer."
Does that relate to the image above or the next page?
A. No, to this above.
Q. And that's what you were discussing before about showing the inflammation evidence that that's been going on for some time? Is that true?
A. This is the chronic foreign body reaction that is ongoing lifelong that happens to the filaments but to the particles as well and this is -- yeah.
Q. Page 73, the top of the page, you have two images, the commentary says,

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"The thickness of this inflammatory infiltrate is around 50 microns, but in some areas with close distance between the filaments, the entire space completely is filled out by this inflammatory infiltrate. In some areas, the accumulation of inflammatory cells indicates a more active, acute inflammatory reaction."

Tell me what it is about those slides that demonstrate that the entire space is filled out by this inflammatory infiltrate.

A. The fact that the entire space between the filaments is completely filled out by this infiltrate is not reflected in these two images.

Q. Okay. What is depicted in these images?

A. You see on the left, you see that I tried to measure the wall, the -- yeah, the inflammatory infiltrate, the thickness of the inflammatory infiltrate very close to the fiber and measured a distance of about 50 microns here.

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On the left side close to the polymer, you see some foreign body giant cells in the red -- in the right picture --

Q. Let's stop on the left for a second.

How many foreign body giant cells do you see?

A. I didn't count them.

Q. How do you determine what they are?

A. They are cells that -- that has confluent nucleus, more than one nucleus, and you have to go to the microscope and have to go through the depth to identify whether it's a giant cell, yes or not. Otherwise, it can be single cells laying over another.

Q. You've used the term "inflammatory infiltrate."

What is included in inflammatory infiltrate?

A. The inflammatory infiltrate, it can be best seen on the right side where you see a lot of these blue nucleus of these cells. These cells indicate this

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inflammatory infiltrate, and as we discussed yesterday, it is a wide field to identify which cells are specifically there. Usually there's about 40 percent that are positive for markers that represent macrophages. There are 30, 40 percent positive for markers that are related to lymphocytes as the main cells, but what's the name is specifically, we're still working on it.

Q. But the presence of the inflammatory infiltrate itself is normal; is that correct?

A. Normal as it is in principle, as it is compulsory of every foreign body reaction.

Q. What is abnormal about --

MR. ANDERSON: Hold on.

QUESTIONS BY MR. THOMAS:

Q. Did I interrupt you? I didn't mean to.

A. In quantity, in quality, that there is it, it is normal. If you mean is it normal in quantity, yeah. For heavy-weight, for a polypropylene, it is quantity that we

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can expect.

If you have other polymers, you won't expect so much.

Q. Okay. What is it about the nature of the inflammatory infiltrate that you see at the top of page 73 creates a risk of complications to Ms. Lewis?

A. The inflammatory infiltrate reflects an area of increased tissue remodelling. So you have an increased number of cell dying there in -- you have an increased turnover, you have an increased proliferation of these cells there because these inflammatory infiltrate has a more rapid turnover than a -- than other tissues.

Q. Is what you see --

A. And, sorry --

Q. I apologize.

A. And, therefore, the presence of an inflammatory infiltrate, that means that there is a chronic wound, means an intensified cell turnover with possible late risks, but -- and an increased risk for migration of the implant.

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QUESTIONS BY MR. THOMAS:
Q. There was no evidence in the Carolyn Lewis case that there was a migration of the implant, was there?
MR. ANDERSON: Objection.
THE WITNESS: I cannot state this from these sections.
QUESTIONS BY MR. THOMAS:
Q. Okay.
A. It's impossible.
Q. Can you state that from your review of the medical records in the case?
Do you know that?
A. Whether it was a real migration?
Q. Yes.
A. Of this? No.
Q. Okay. Are the findings that you've described in response to my questions concerning the images at the top of page 23 consistent with the reaction that any polypropylene mesh would have?
A. With any heavy-weight, small pore polypropylene meshes, they're completely

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consistent.
Q. Okay. Middle of page 73, what do we see?
A. We see, again, the holes where the polymers has been. You see an inflammatory infiltrate around it and it is -- it is an area where a folding and doubling of the layers can be seen, but not in this image, unfortunately, because we are limited with -- the lowest magnification is 40, and, therefore, it is impossible to get a good overview. To really -- either -- no, except of looking at the slides with a microscope where you can see that the configuration of the meshes are not in a plane area any longer, the alternative would be to make five, six images and to place them together.
As we made it, we have seen it already in some of the old documents where we made these long combination of various pictures to see the configuration of the meshes.
MR. ANDERSON: You said plane,

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you mean plane?
THE WITNESS: A plane, yeah.
QUESTIONS BY MR. THOMAS:
Q. So is it fair to understand that it's your opinion that your microscopic review of these slides shows you that there was folding demonstrated, but this slide that's in the middle, this image that's in the middle of page 73 does not show that?
A. That is -- that is correct.
Q. And you need to see the entire field in order to understand what you believe to be folding demonstrated by that slide?
A. That is correct.
Q. Is the rest of the action -- excuse me.
Is the rest of the reaction in the middle of page 73 that you've described consistent with the foreign body reaction to every heavy-weight, small pore mesh?
A. Yes.
Q. It is?
A. Yes.
Q. Thank you.

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MR. ANDERSON: He was waiting to make sure you distinguish heavy-weight, small pore. That's why he was smiling.
QUESTIONS BY MR. THOMAS:
Q. Page 73, the lower image, what does the lower image depict?
A. This is an image, I believe, that the -- the expression of folding is related to the lower image there. There you have the magnification of 40 and there you have a wider view of the meshes. And but in reality when you look to the section, you see further on where the mesh is going to. Here you have -- you see several places where the polymer has been -- this is hardly to believe that this is the mesh with the -- in plane area without doubling or folding that you get this section here.
Q. And help me, I am sorry, it's either late in the day or I'm not very smart, maybe both. The white areas in those, are those actual polymers?
A. These are some of the few parts

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where the polymers are still in place. The others you only see the holes, but, of course, there has been some polymers now laying in between or being removed by the knife.

Q. So in order for you to conclude that there's been folding here, you count both the polymers that you see and the holes where you suggest that polymers have been and conclude from that that there had to be folding?

A. Yes.

Q. Anything more than that that supports your contention that there's folding?

A. No. It is the appearance of the holes where the polymers has been and the geometrical configuration of these in a section.

Q. Is there anything else remarkable about the lower slide on page 73 other than your testimony about the folding?

A. No.

Q. Is the foreign body reaction

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depicted in the lower slide on page 73 consistent with heavy-weight, small pore meshes?

A. Yes.

Q. On page 73 at the top, what do we see?

A. This is an S100 staining and in the little of the left part of the image, there I expect there has been a polymer. It was removed by the preparation, and you have some areas with a brown staining there and this is consistent with the presence of a nerve in the area.

As we have three sections which are very close to each other, if you're looking to all three sections with S100, you see that it's not an artifact -- an artificial staining in one slide, but it is an ongoing structure going through all of these three slides so that I have no doubts that there's a small nerve.

Q. Okay. And as we said before, the mere presence of a nerve is not remarkable by itself?

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A. Not for me, but there are people who are -- for whom this is an important message.

Q. In the slides that you analyzed for Ms. Lewis, did you find any evidence of a neuroma?

A. No.

Q. Did you find any evidence of infection?

A. If I remember correctly, there was an area where you have an enhanced or where you have an intensified inflammatory infiltrate in this field. I know from Professor Klosterhalfen that the definition of infection sometimes is only the appearance of some more inflammatory cells than usually so, therefore, I cannot state it for sure that there has been one.

Q. Do you have an opinion to a reasonable degree of scientific certainty based on your review of the slides that's been provided to you that Ms. Lewis has an infection because of her mesh?

A. I don't have sure proof that

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there was an infection.

Q. So is it fair to understand you don't have such an opinion?

A. Have an opinion that I did not see it.

Q. Great.

MR. THOMAS: Can we take a break, please?

(Off the record at 3:54 p.m.)

QUESTIONS BY MR. THOMAS:

Q. Doctor, I want to direct your attention to the chart that appears at the end of your report where you compile your findings from the -- your review of the slides and the spreadsheet has columns O, P, Q, R where you record what you found from your review of the slides.

Is that correct?

A. That is correct.

Q. The first column P says bridging, 1, less than 5 percent; 2, 5 to 30 percent; 3, 30 to 80 percent; and 4, greater than 80 percent.

How did you measure that?

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A. If you look to the entire section, you have some areas where you can identify something like a pore because you see some filament on the one side and on the other side. And if you look to the space in between two adjacent filaments, then you can assume this to be a pore. And if this is filled, if the area between the two neighboring filaments, if this is filled by fat tissue, I notice this in this chart and I only saw one or two times in all these sections that I got the image where I saw two filaments and the space in between was not filled by scar tissue.

So if I code this with more than 80 percent, then you got in all these sections four.

Q. Is 80 percent consistent with what you've described as scar plate formation?

A. Scar plate formation has been a term in a specific period of time. I think it's consistent.

Q. Okay. Well, do you use a

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different term now to describe what you find when you find bridging at greater than 80 percent?

A. You have to be very careful when using the term "scar plate" because some people are thinking of the macroscopically appearance and some are thinking of the microscopically appearance. So if you made it clear, no problem with this, but you have to be very precise in the definition of what you're thinking of.

Overall, this is completely in accordance what we expect that we have predominantly bridged or this -- these pores filled by scar tissue, yeah.

MR. ANDERSON: So the first one was macroscopically and then you said microscopically.

THE WITNESS: Microscopically.

QUESTIONS BY MR. THOMAS:

Q. So when you say 80 percent filled with scar, does that mean that there is not room for capillary vessels?

A. No. You have capillary vessels

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in scar tissue as well. So it means that you have scar and scar is mainly consistent with collagen leading to wound -- or being major -- majorly important for the wound contraction and some fibroblasts there and, of course, vessels. The only area where you hardly have vessels is very, very close to the polymer fiber.

But the appearance of vessels is no indicator of scar plate or scar net or --

Q. Do you know whether this scaling that you've done for the bridging is a method that's generally accepted by pathologists to look at mesh explants?

A. I made this scaling just for these cases to give -- to be able to give an impression of what I've seen there.

Q. What is the significance in your judgment of scaling of less than 5 percent? Excuse me, strike that.

What is -- what is the significance in your judgment of bridging less than 5 percent?

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A. You have to understand what we tried in these 15, 20 years is not only to make a qualitative description of the tissue reaction but to find some quantitative an -- or way to make a quantitative analysis there. And this is very difficult because from the methods. So, therefore, we make -- we introduced -- there has been some time when we use image analyzing. Now we're coming back to this coding, and the coding less than 5 percent means usually that you never see a bridging in this specimen.

Q. Why do you use 5 to 10 percent as your next range?

A. It is for scientific reasons you should have at least four different scoring levels, otherwise, you very likely go to the middle and then you will not see any difference so you need at least four different levels and you have to start from the extremes always and none and then you have to fill in between. I have no problem to make it different. And I made this coding before looking to the images, and, therefore,

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I was bound to this.
Q. Have you ever used this type of coding before in analyzing mesh explants?
A. We used such a type of coding very, very often to give a semi-quantitative analysis of our staining, yeah.
Q. When you say "we," who do you mean?
A. I, in my projects where we analyze these tissue samples, that is a major aspect before we starting the analysis to define the parameters and to define the coding, how to make the readout there.
Q. Okay. Do you always use the same numbers?
A. No. It varies from the specific question there, but it is about four to five.
Q. Okay. Under folding or shrinkage, that's "or," so if it's either folding or shrinkage, you capture it, correct?
A. Yes.
Q. Didn't we decide that every

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mesh is going to fold -- excuse me, didn't we decide that every mesh is going to shrink approximately 20 percent?
A. What I have been thinking of when looking for this folding was a double-layer structure which I cannot explain by the video I saw where the sling is implanted in a plane area, but when you have the impression that you have two or three layers of mesh materials on top of each other, I would say that there's a folding.
And shrinkage is if you have a configuration as a -- with a folding there in this area.
Q. So this says "folding or shrinkage."
A. Yeah.
Q. If you found shrinkage of 20 percent, would that be a positive finding?
A. This is a description of what can be seen there. What is the appearance of --
Q. I understand that.
What I'm trying to understand

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if you identified shrinkage of 20 percent, would that be a positive finding in your chart?
A. I didn't measure the degree of shrinkage. It was not possible to do so. It was just a configuration of the mesh.
Q. So if you saw any shrinkage at all, it would be a positive finding?
A. If I had the impression that the configuration of the mesh changes by pushing together, going to waves or by doubling, these are the two different things that indicates either shrinkage, pushing it together, or folding --
Q. The only reason I'm asking, Doctor, is because I thought we decided that all wounds shrink to some extent, generally at least 20 percent.
And so as I understood your testimony earlier, that means that every mesh explanted would be a positive finding here.
A. Sorry, it may be my fault that I call it shrinkage. I should have named it waving form or deformation of the shape due

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to shrinkage.
Q. Okay. The last category, "Nerve contact within one millimeter of sling."
Have we -- do we agree that there's nothing remarkable about nerve contact in itself? The nerves are going to be --
A. The fact that there are nerves in this place is not remarkable. The fact that these nerves are laying in this scar tissue gives a good explanation why some patients have chronic pain.
Q. Okay. And if PVDF mesh is placed for the treatment of stress urinary incontinence and comes in contact with a nerve, you would have the same risk of chronic pain, correct?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: I would assume that if the nerve is laying in the fields of scar that is close to PVDF slings that there will be the chance

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for chronic pain as well.
However, the overall chance to get entrapped into scar tissue, I would expect is much lower and, therefore, the risk for pain is much lower when using large pore PVDF structures.
QUESTIONS BY MR. THOMAS:
Q. But we don't know that until we study it, correct?
A. We note from all our experience, from all our work that the risk for chronic pain decreases by using large pore structures and decreasing the amount of inflammatory reaction, yes, we know it already.
Q. From animal studies?
A. No. From clinical studies as well. We can go back to the guidelines where it is favored, the advantage of large pore meshes because of less chronic pain.
Q. Have we covered all of your opinions with respect to Carolyn Lewis?
MR. ANDERSON: Objection.

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THE WITNESS: I have the impression that we covered a lot. There are --
QUESTIONS BY MR. THOMAS:
Q. I'm talking about Carolyn Lewis specific to the mesh analysis that you did.
Have we covered it all?
MR. ANDERSON: Objection. With "whether you've covered it all."
MR. THOMAS: Well, I'm trying to go to his report, Ben, and I think I've covered every sentence in the report that deals with the mesh. If there's something that's in the report that I don't know about --
MR. ANDERSON: The only issue, Dave, is that he said that a lot of the slides that you can't put those types of fields into a one-dimensional report, and I told you that I would provide you mine and you were going to send me your guy's. So whether or not there are similar but expanded opinions based upon a larger review of

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a slide, that's the only thing I can think of. If that makes sense.
MR. THOMAS: I just want to make sure I haven't missed something in his report in the information that you provided to me here that I need to explore.
MR. ANDERSON: Anything significant.
MR. THOMAS: Either you or the doctor can tell me, if there's something else I need to explore, I want to do it, otherwise, I'm about to quit.
MR. ANDERSON: I think he's listed in his report in the grid and I think you've covered most all of that for her and I don't know if you covered all of the path slides that are in the back or not.
MR. THOMAS: Well, that's the problem is I don't know which ones are hers.
MR. ANDERSON: Yeah, you do.

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The grid says 13-23 and then the images correspond. That's one of the reasons I gave that to you to try to make that a little easier.
MR. THOMAS: Thank you.
Are they in order?
MR. ANDERSON: They're in order. Yours is in order of this grid, but hers should be last.
MR. THOMAS: They're not. No.
MR. ANDERSON: They're grouped together.
MR. THOMAS: Okay.
MR. ANDERSON: There we go. If you find the dark ones, it makes it easier.
MR. THOMAS: The first one that I have here appears to be -- and they're not numbered so I can't give you a page number, but in Exhibit 11, the first one that I have appears to match the one on page 71.
MR. ANDERSON: And that's why we said we have to go through them and

see if they're -- all of them are listed. We just have to count them. There's 13 images in the back that I count of the report and you're in the middle of them right now.

MR. THOMAS: Let's go to the last one.

MR. ANDERSON: Show me which slide.

QUESTIONS BY MR. THOMAS:

Q. The last slide that I have in front of me, I'm sorry, it's not numbered, but it's BAL 13-23, which is the patient identifier. On the right, it has a scale of 100 microns, and in the middle of the slide, it shows what appears to be a measurement of 43.15 microns.

Is that a -- that's the one on page 73?

A. Uh-huh.

Q. Is that right?

A. Seems to. Yeah, I will agree.

MR. THOMAS: So you counted 13?

MR. ANDERSON: I think that's

right.

MR. THOMAS: And there are 13 in the report.

(Klinge Exhibit 25 marked for identification.)

QUESTIONS BY MR. THOMAS:

Q. Let me mark as Deposition Exhibit Number 25 the chart that we've been consulting, correct?

A. Yes.

Q. And that's where you recorded your findings from your review of the slides that we've been discussing, correct?

A. Yes, these are my results.

Q. And it also includes the information that Mr. Anderson provided about the chain of custody and the source of documents that you received, fair?

A. Yes.

Q. Dr. Klinge, did you ever tell Ethicon that they should not sell the Prolene® mesh used for the treatment of stress urinary incontinence?

A. No.

MR. THOMAS: Those are all of the questions I have.

CROSS EXAMINATION

QUESTIONS BY MR. ANDERSON:

Q. Dr. Klinge, you were asked a few questions a few minutes ago by counsel regarding whether or not you had a residency or a fellowship in pathology.

Do you remember those questions?

A. Yes.

Q. Dr. Klinge, approximately when did you begin reviewing pathology slides of explanted meshes?

A. We -- I started to have a look through the microscope to these explanted meshes in 1994.

Q. And was that as part of the work with the IZKF-BIOMAT cross-functional team at Aachen University?

A. It was in relation to this project with the IZKF in collaboration with Professor Klosterhalfen at that time.

Q. Is it fair to say that

Dr. Klosterhalfen trained you as a pathologist to review the histopathological slides of foreign body reaction to implanted meshes?

MR. THOMAS: Object to the form of the question.

THE WITNESS: Yes.

QUESTIONS BY MR. ANDERSON:

Q. You said "yes"?

A. Yes.

Q. Since that time in 1994 when you first began looking at slides from either animals or human tissue of explanted meshes, approximately how many times have you reviewed such slides and analyzed them? How many slides?

A. How many slides? It's difficult to estimate, but I've -- I estimate it's more than 25,000.

Q. And as part of your review of over 25,000 slides of the histopathology of explanted meshes, have you also published on some of those reviews?

MR. THOMAS: Object to the form

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of the question.
QUESTIONS BY MR. ANDERSON:
Q. In the peer-reviewed literature?
A. Yes. Yes.
Q. And have there been times where you have published in the peer-reviewed literature where you were the only pathologist that was reviewing the slides for the work that was contained in the study?
A. Yes.
MR. THOMAS: Object to the form of the question.
QUESTIONS BY MR. ANDERSON:
Q. You said "yes"?
A. Yes.
Q. Okay. And have you presented at Congresses and conferences to your colleagues and others with regard to your analysis of histopathological review of slides from explanted tissue in either humans or animals?
MR. THOMAS: Object to the form of the question.

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THE WITNESS: Yes. And it is a common procedure that a scientist made his own personal analysis of the tissues and made the analysis and the presentation of these data by himself.
QUESTIONS BY MR. ANDERSON:
Q. A little while ago counsel was asking you some questions about your choice of using the S100 staining with regard to your review of these 22 explants.
Do you recall that part?
A. Yes.
Q. He also asked you some questions to which you responded that this was something that you and Bernd Klosterhalfen had discussed many years ago about the choice of S100.
Do you remember that part of your question?
A. Yes.
Q. When you were answering these questions, you were talking -- strike that.
You never talked to Dr. Klosterhalfen about whether to use S100

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for this case; is that correct?
A. Yes, that's correct, I never talked to him.
Q. Yesterday counsel was asking you some questions about this time period from 1994 to 2000 when you were in this cross-functional team with the IZKF-BIOMAT in Aachen with the group Ethicon Norderstedt.
Do you recall that part of your testimony?
A. Yes.
Q. He asked you whether that time period dealt with the treatment of stress urinary incontinence.
So my question is this:
Dr. Klinge, do you consider that your work that you did in the '90s in developing VYPRO and in working with this BIOMAT team, the publications that you've done over the last 20 years, the conferences you've spoken at and all of the work that you've done in this field of biomaterial research and the tissue response to surgical meshes as well as your work as a hernia surgeon relates equally to

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hernia surgery mesh and the body's reaction to it, pelvic organ prolapse mesh and the body's reaction to it and sling mesh and the body's reaction to it?
MR. THOMAS: Object to the form of the question.
THE WITNESS: In regard to the biological response to these meshes, to these hernia meshes, there are a lot of similarities that allows us to make conclusions for both of this. There are, of course, severe differences or significant differences in regard to functional analysis or biomechanics, but the tissue reaction to a polymer is a lot of similarities.
QUESTIONS BY MR. ANDERSON:
Q. Is one of the similarities that all of this work that we've been discussing for the last two days and the things that I listed in my former question to you help scientists like yourself try to predict the tissue response to particular surgical meshes?

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MR. THOMAS: Object to the form of the question.
THE WITNESS: Yes, in fact, it is this knowledge that we acquired in these years that allow us to make this analysis, to define requirements for textiles in this field and it is usually very appreciated when we present our experiences of these 15 years to urogynecologists.
QUESTIONS BY MR. ANDERSON:
Q. Thank you, Doctor.
Yesterday counsel asked you some questions as well regarding whether or not anyone in Aachen had a direct role in the development of ULTRAPRO™.
Do you recall those questions?
A. Yes.
Q. Whether or not anyone had a direct role in the research and development of ULTRAPRO™, do you consider the work that you and your team in conjunction with Ethicon did on VYPRO to be the foundational principles upon which ULTRAPRO™ was designed?

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A. I think it was quite clear that ULTRAPRO™ was the successor of the VYPRO, and it just replaced an oligofilament mesh materials by monofilament and what we tried with the IZKF funding where we tried to do and realized with the PVDF that was done by Ethicon with polypropylene and Monocryl. And as a consequence, I guess that, therefore, I got royalties for the ULTRAPRO™, not only for the VYPRO because of this close relationship.
Q. So is it fair to say that you were receiving royalties for ULTRAPRO™ sales at the same time that you were telling Ethicon that you believed and that the Aachen group believed that PVDF was a superior material to polypropylene?
MR. THOMAS: Object to the form of the question.
THE WITNESS: There is an overlapping time period there.
So, again, just to make it clear, ULTRAPRO™ took over the principles of the VYPRO, the large pore concept, the material reduced

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concept, therefore, it includes what we have collaborated for the VYPRO, but the specific details of the textile construction, there we haven't been involved.
QUESTIONS BY MR. ANDERSON:
Q. Okay. Yesterday counsel asked you some questions about Exhibit 9, which were the meeting minutes from the Suvretta meeting in 2003 in St. Moritz.
Do you remember that?
A. Yes.
Q. And he asked you some questions about the part of your presentation where you were discussing whether a scar plate or a scar net might begin to -- that would appear to be between 600 and 800 microns.
Do you remember that part of your testimony yesterday?
A. Yes.
Q. I want to show you what we've marked as Klinge Deposition Number 26 to your deposition.
(Klinge Exhibit 26 marked for

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identification.)
QUESTIONS BY MR. ANDERSON:
Q. Do you recognize this publication?
A. Yes.
Q. And this is a publication in 2002 in the Journal of Surgical Research?
A. Yes.
Q. And are you one of the authors along with those from the BIOMAT -- the IZKF-BIOMAT group?
A. Yes, I was the author.
Q. And if you turn to the very last page under the "Acknowledgements" section as well as at the bottom of the page, does this indicate who provided funding?
A. Yes.
Q. And which company provided funding to this research?
A. Most supported by Ethicon and by the IZKF-BIOMAT.
Q. Because this was the time -- this is the time that you're working closely with them on developing VYPRO?

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A. No, this was after this time where we developed the VYPRO, but it was the time where we worked close together and had several ongoing projects together.

Q. And if we turn to page 213 of this article from 2002, if we look to the left-hand column, down where the words begin "As a result," what does that say?

Does it say, "As a result, the large pore sized greater than 2-millimeter mesh is integrated in a loose network of perifilimentary granulomas and plenty of fat tissue in between. Whereas the monofilament mesh with its smaller pores almost exclusively is imbedded into granulomas and scar tissue which bridges the whole pore diameter of less than 1 millimeter"?

Did I read that correctly?

A. Yes.

Q. Does that language that you've seen appear in Ethicon documents?

A. Yes.

MR. THOMAS: Object to the form of the question.

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THE WITNESS: Yes, I've seen it in many documents, and I'm sure I have repeated many of these phrases yesterday and today. Because it's still our belief.

QUESTIONS BY MR. ANDERSON:

Q. And given that -- strike that.

So this journal article that was published in -- based upon studies that were funded, at least in part by Ethicon, was in 2002, and your presentation in St. Moritz was in 2003.

So my question is you've listed a limit of 1,000 microns in the 2002 article with regard to a limit where fibrotic bridging may be seen, whereas in the panel discussion in Suvretta in 2003, you listed 600 to 800 microns.

Can you please explain that?

A. At that time, we had -- we made several attempts to make measure the pore and the bridging and we started at that time with the Marlex mesh and before I saw somewhere in the documents that there is a PowerPoint

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presentation in 2000, 2001 showing the distribution of the pores based on the Marlex mesh and there we indicated that there may be a -- that in these specimen that we measured at that time there was a limit in between 600, 800 microns.

In the other article, we want to express that a -- wanted to say or to be on a -- in a range that -- where you can expect that you get pores without this bridging, there we find this is 1 millimeter and in between, I guess, there has been the experiment that later on has been published by Conze with IPOM where we again measured all of these distances.

So, yeah, we learned that it depends from the polymer that is affected by the animal model there, but, however, we wanted to give a range or to give a hint where the border lays and, therefore, we said 1 millimeter.

If you look to the documents later on, in the presence of tension, Klosterhalfen advised 3 millimeters in some

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meetings there, and so I've no disagreement to this. So you see that there was a evolution of these advises and you have to be carefully looking to the specific conditions in what condition this was expressed there.

Q. And during that time period in the late '90s and early 2000s, were most of the heavy-weight, small pore meshes somewhere in this 600 to 1,000-micron pore size?

MR. THOMAS: Object to the form of the question.

QUESTIONS BY MR. ANDERSON:

Q. In a linear measurement?

A. Yeah. We didn't realize that the Prolene® is around this 1 millimeter in this. And maybe that there will be an upcoming question whether this millimeter is enough or it's not enough. If we have known at that time that this may be a problem, we would have thought a little bit more precisely to find maybe another border, to find another border there.

Q. Whether the limit is at 950 microns and 1,050 microns, is it safe to

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say that in all of the explants of Prolene® old construction 6-mil mesh, whether it was in the explants that you looked at from animal studies back during your time working with Ethicon or in any of the explants that had been done both in the 1,000 hernia explants as well as the greater than 400 explants that have been looked at from the pelvic floor, have you consistently had an observation with regard to the way Prolene® old construction 6-mil mesh that's used in the TVT® slings reacts in the tissue in terms of its pore size?

MR. THOMAS: Object to the form of the question.

QUESTIONS BY MR. ANDERSON:

Q. Have you noticed any sort of pattern or consistency there?

MR. THOMAS: Same objection.

THE WITNESS: In all of these sample that we had a look to it, Prolene® behaves as a heavy-weight, small pore mesh regardless whatever figures are printed out. The

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morphology of the tissue examination, with the extent of the geometry of the scar formation makes it clear that the old Prolene® is a -- behaves like a small pore -- heavy-weight, small pore mesh.

QUESTIONS BY MR. ANDERSON:

Q. And a few minutes ago when counsel was asking you some questions about the pathology slides and he said -- when you're looking at these slides of TVT® meshes, he asked you is this a normal fibrotic response or a normal tissue response.

Do you remember those types of questions?

A. Yes.

Q. And you said -- your testimony was normal or what we usually see with regard to a heavy-weight, small pore mesh.

Do you remember that part of your testimony?

A. Yes, I remember that part.

Q. Is that what you're referring

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to now with regard to the fibrotic bridging you've seen with Prolene®?

MR. THOMAS: Object to the form of the question.

THE WITNESS: Again, it is clear that it is normal for a high risk -- with a mesh for high risk for fibrosis. For a high-risk mesh, this is a normal reaction.

QUESTIONS BY MR. ANDERSON:

Q. And do you believe that the Prolene old construction 6-mil mesh used in TVT® is a high-risk mesh with regard to heavy-weight, small pore mesh that leads to fibrotic bridging and complications in patients?

MR. THOMAS: Object to the form of the question.

THE WITNESS: It's a high risk in regard to the extent of inflammation, scarring, shrinkage, dimension or the amount of material.

QUESTIONS BY MR. ANDERSON:

Q. And do you hold that opinion to

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a reasonable degree of medical and scientific certainty?

A. Absolutely. I'm convinced of it and there's huge evidence for this.

(Klinge Exhibit 27 marked for identification.)

QUESTIONS BY MR. ANDERSON:

Q. I show you what I've marked as Klinge Exhibit Number 27.

Have you seen this article before entitled, "The Argument for Light-Weight Polypropylene Mesh in Hernia Repair" from Surgical Innovation in 2005?

Have you seen this before?

A. Yes, I've seen it before.

Q. And do you know these authors, William Cobb, Kent Kercher and Todd Heniford?

A. Yes, I know them.

Q. And is Todd Heniford the hernia surgeon that you mentioned with reference to the Suvretta conference in 2003?

A. Yeah, I met him there and at several conferences in Europe as well.

Q. And you understand after

reviewing materials that I've sent you, that Dr. Heniford is an expert for Ethicon in this litigation?

A. Even more, he's an expert for the argument of light-weight polypropylene. Of the use of light-weight meshes.

Q. If we turn to Dr. Heniford's publication, on page 2, which on this publication is on page 64 at the top left of Exhibit 27, what is the weight listed for Prolene®?

A. Prolene® here, it's given 105-gram per square meters.

Q. And it's lighter or heavier than Marlex?

A. It is heavier.

Q. And if we turn over to page 67 of this article by Dr. Heniford and his colleagues, do you see the section "Degree of Shrinkage"?

A. Yes, I see it.

Q. And reading under there, "One concern with the long-term implantation of mesh is the amount of shrinkage or passive

compression the material undergoes. All available meshes regardless of their composition, experience a 20 to 50 percent reduction in their initial size."

Did I read that correctly?

A. Yes.

Q. Was that the state of knowledge as of 2005 based upon your understanding and your work that meshes could shrink from 20 to 50 percent?

MR. THOMAS: Object to the form of the question.

THE WITNESS: Yes, I agree.

QUESTIONS BY MR. ANDERSON:

Q. Is that part of what you were testifying to earlier when answering Mr. Thomas's questions regarding amount of shrinkage that you can expect from polypropylene meshes in the human body?

A. It's in accordance to what I said.

Q. If you turn over to page 68, in this Heniford article, if you look down to the second -- the column on the right in the

sentence in Dr. Heniford's article, it says, "In contrast, the small pore mesh was incorporated entirely in perifilimentary granulomas and scar tissue which bridged the whole pore diameter of less than 1 millimeter."

Did I read that correctly?

A. Yes.

Q. And we have the diagrams down below showing that, "A 4-millimeter pore size will not show the granulomas touching of a light-weight mesh, whereas a 0.8-millimeter pore size does have the granulomas touching of a heavy-weight mesh."

Do you see that?

A. Yes, I see that.

Q. So according to this article, would Dr. Heniford and his colleagues' opinions be consistent with your own with regard to the percentage of shrinkage of meshes in vivo as well as the limit of around 1,000 microns to prevent fibrotic bridging?

MR. THOMAS: Object to the form of the question.

THE WITNESS: All of these statements by -- published or concluded in this manuscript confirms my opinions in regard to shrinkage and required pore size to prevent bridging.

QUESTIONS BY MR. ANDERSON:

Q. And if we look to the left under the paragraph that begins, "In a dog model," does that paragraph indicate that polypropylene meshes shrink 30 to 50 percent of their original size within two to six months after implantation.

Do you see that?

A. Yes, I see it.

Q. Is that consistent with the opinions that you've stated to counsel here today?

A. Yeah. It is -- it confirms that the extent of shrinkage is higher in heavy-weight -- when using heavy-weight materials and can be reduced by using material-reduced meshes.

Q. And these ideas of the amount

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of contraction that could be expected in vivo of polypropylene meshes, was this information that Ethicon was aware of as a result of your work with them going back to the '90s?

MR. THOMAS: Object to the form of the question.

THE WITNESS: Yes. And yeah.

MR. THOMAS: Can we take a real quick break?

MR. ANDERSON: Yeah.

MR. THOMAS: Just ten seconds.

(Off the record at 4:44 p.m.)

QUESTIONS BY MR. ANDERSON:

Q. I don't remember the exhibit that we had with Professor Klosterhalfen with this document the other day, but if we have the minutes from 2007.

I'm going to show you what we marked the other day as Klosterhalfen Exhibit 11, which are the minutes from the meeting in Norderstedt in 2007.

You've seen this document before?

A. Yes, I've seen it.

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Q. And at that meeting, if you turn to page 2, do you see a heading "Factors Related to Mesh Shrinkage"?

A. Yes.

Q. By a Ms. Spychaj?

A. Yes.

Q. S-p-y-c-h-a-j.

MR. THOMAS: Object to the form of the questions related to that document. Was he at that meeting? Was he shown being in attendance?

MR. ANDERSON: I don't know. It doesn't show him being there.

MR. THOMAS: That's what I thought. Just a continued objection to his comments because he wasn't there.

MR. ANDERSON: Sure. I don't think he has to be present at meetings to be able to look at the PowerPoints that were there.

QUESTIONS BY MR. ANDERSON:

Q. And this PowerPoint entitled "Factors Related to Mesh Shrinkage," you've

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seen this document before?

A. Yes, I've seen it.

Q. And if we turn over into the document where it says "pore size" from this presentation in -- at Ethicon February 23, 2007, does that page indicate on a slide by Kirsten Spychaj, "Small porous meshes less than 1 millimeter lead to fibrotic bridging and increase shrinkage"?

A. Yeah.

Q. "Large porous meshes allow for a better and faster tissue ingrowth and less shrinkage and contraction"?

A. That is a correct summary.

Q. And down below where it says, "less than 1 millimeter" in the three little circles, these are drawings that you've seen before?

A. Yes, I've seen it.

Q. And these little red dots, would those indicate the peri-filamentous granulomas that you were referring to earlier?

MR. THOMAS: Object to the form

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of the question.

THE WITNESS: Maybe it can be interpreted in this way.

QUESTIONS BY MR. ANDERSON:

Q. So this would be a depiction of the size of pores after implanted in the body as a depiction of that, correct?

MR. THOMAS: Object to the form of the question.

THE WITNESS: That is correct. It's quite similar to the images that have been in the publication from Heniford.

QUESTIONS BY MR. ANDERSON:

Q. And have you seen this image of pores less than 1 millimeter leading to fibrotic bridging that we see here on -- I'll have to mark this as Plaintiff's Exhibit 28.

(Klinge Exhibit 28 marked for identification.)

QUESTIONS BY MR. ANDERSON:

Q. Is this an image that you've seen many times throughout the Ethicon documents that you've reviewed over the last

two years in these litigations?
A. Yes, many times. Many times. And I've never seen any document showing that this is not a fact.
Q. Have you seen in any of the peer-reviewed literature in the last 20 years anyone who has disputed the fact that you need greater than 1 millimeter pore size to prevent fibrotic bridging in the tissues?
MR. THOMAS: Object to the form of the question.
THE WITNESS: No, I don't know. No, any study, any discussion that claimed to have facts that are in contradiction to this finding, to this estimate, to this interpretation.
QUESTIONS BY MR. ANDERSON:
Q. In the worldwide peer-reviewed literature over the last 20 years, have you seen any scientist or surgeon who has published regarding looking at -- has published regarding studies either looking at animal explanted mesh or human explanted mesh who have indicated that light-weight, large

pore meshes versus heavy-weight, small pore meshes, that the heavy-weight, small pore meshes induce fibrotic bridging and scarring and contraction, whereas larger pore, lighter weight meshes do not? Has anyone in 20 years refuted those findings based upon the indications that I just gave you?
MR. THOMAS: Object to the form of the question.
THE WITNESS: Do less. Larger pores do less fibrotic reaction, but I never saw or were confronted with someone disputing this findings.
QUESTIONS BY MR. ANDERSON:
Q. Have you ever seen in the peer-reviewed worldwide publication in the last 20 years any researchers other than yourself and Dr. Klosterhalfen who have reviewed as many explanted meshes from both animals and human beings for hernia, POP and SUI and reported on those in the worldwide literature, any other scientists other than the two of you?
MR. THOMAS: Object to the form

of the question.
THE WITNESS: No.
(Klinge Exhibit 29 marked for identification.)
QUESTIONS BY MR. ANDERSON:
Q. Showing you what we will mark as Klinge Exhibit 29.
Showing you what we have marked as Plaintiff's -- I am sorry, as Klinge Exhibit 29, have you seen this -- have you seen this e-mail before during this litigation?
A. No.
Q. Okay. An e-mail from Joerg Holste to Jonathan Meek dated April 22, 2009.
Do you see that?
A. Yes, I see it.
Q. And in the first line, "Jonathan, the border for scar plate formation in small pore standard weight meshes was set around 1,000 microns."
Do you see that?
A. Yes, I see it.
Q. And is this Joerg Holste that

you have worked with since the '90s going back all the way back to your IZKF-BIOMAT work with Ethicon to develop VYPRO?
A. That's true.
(Klinge Exhibit 30 marked for identification.)
QUESTIONS BY MR. THOMAS:
Q. Showing what we will mark as Klinge Exhibit 30.
This is a Klinge -- sorry, this is a clinical expert report from Piet Hinoul, medical director, Ethicon, department of medical affairs.
Do you see that?
A. Yes, I see it.
Q. It's dated September 25, 2012?
A. Yes.
Q. If you turn over to the page four pages back, which ends in Bates number 5782, under Prolene®, what does he list as the maximum pore size in millimeters?
A. The pore size of less than 1 millimeter.
Q. Thank you.

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Showing you what we will mark as Klinge Exhibit 31 -- wait a minute. Actually you -- strike that.

Showing you what was previously marked by counsel as Klinge Exhibit 21. There was this International Urogynecology Journal from Moalli and some of her colleagues entitled "Tensile Properties of Five Commonly Used Midurethral Slings Relative to the TVT®" from May 2008.

Do you remember counsel showing you this?

A. Yes, I remember.

Q. And he showed you on the top of what is page 57 of this article, he showed you the pore size of Gynecare being listed as 1379.

Do you see that?

A. Yes, I see it.

Q. And at the top of that under Table 1, it says, "Textile Properties Provided by the Manufacturers."

Do you see that?

A. Yes, I see it.

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Q. Did you see there -- strike that.

There was some questions by counsel about their measurements of the pore size in this article.

Do you see anywhere in this article where these authors measured these pore sizes?

A. No. As it is indicated there, they took it from the manufacturer.

(Klinge Exhibit 31 marked for identification.)

QUESTIONS BY MR. ANDERSON:

Q. Showing you what we will mark as Klinge Exhibit 31, under "Proprietary Mesh," do you see here where they list there under "Proprietary Mesh," it says, "Largest pore size"?

Do you see that?

A. Yes, I see it.

Q. And do you see 1379 -- 1,379 microns listed here by the manufacturer?

A. Yes, I see it.

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Q. Other than being listed in this -- I am sorry, let's go to the cover page.

It has, "Demand the most proven technology when selecting a midurethral sling. Make data and safety your choice" with the surgeon on the front.

Do you see that?

A. Yes, I see it.

Q. And in this document where they list 1,379 microns --

A. Yes.

Q. -- based upon your review of the depositions and the testing and the porosity and pore size evaluations by numerous Ethicon employees, have you ever seen any indication in any of those that there was a measurement of a pore size of Prolene® of 1,379 microns for the mesh used in TVT® anywhere in your review?

MR. THOMAS: Object to the form of the question.

QUESTIONS BY MR. ANDERSON:

Q. Other than on this promotional

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document by Ethicon, based upon your review of the depositions of Dan Burkley and all of the other documents that you've seen, have you ever seen them come up with a number of 1,379?

A. No, I didn't see it.

Q. In fact, according to their medical affairs director, Piet Hinoul, in this 2012 expert report, which was Klinge Exhibit 30, he says it's less than 1 millimeter, correct?

A. Yes.

MR. THOMAS: Object to the form of the question.

QUESTIONS BY MR. ANDERSON:

Q. Going back to this Moalli article -- turning to this page where it says Figure 4, is this uniaxial testing that's being shown?

A. Yes, it's uniaxial testing. It's quite similar to what we did with Professor Mühl's machine.

Q. And these are the photos of A, B and C that you have as images in your

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report, correct?
A. Yes.
Q. Okay. Doctor, I want to ask you one more thing about this Prolift+M® document.
Here it shows a weight of what would be 76 grams per centimeter squared.
Do you see that?
A. Yes, I see it.
Q. So this would be a lighter Prolene® mesh than actually the old construction 6-mil mesh, correct?
A. Per the other -- yes.
Q. So would you expect the pore size of the heavier weight Prolene® mesh to be just as small, if not smaller, than the Prolene® 76 grams per meter squared mesh?
MR. THOMAS: Object to the form of the question.
THE WITNESS: It is difficult to -- for me to find this relation between weight and pore size.
QUESTIONS BY MR. ANDERSON:
Q. And when you were looking at

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the pore size of Prolene® with Dr. Klosterhalfen back in the late '90s and early 2000s, was it your best estimate as of that time that the old construction 6-mil Prolene® fibers used in all of the TVT® devices had a pore size of 1,000 microns or less?
MR. THOMAS: Object to the form of the question.
THE WITNESS: It is when we made this linear measurements in one dimension, we got figures around 1 millimeter. When we made analysis by defining the area, we got figures around 1 millimeter. So it is Prolene® has pores in this area.
QUESTIONS BY MR. ANDERSON:
Q. Over time I think -- over time I think you were telling counsel that rather than using a linear dimension that the pore diameter dimensions and the distribution of the pore area of 1 millimeter in diameter became more important to you than the linear measurement.

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Do you remember that part of your testimony?
A. Yes. Yes.
Q. Okay. Do you consider the Mühl testing to be instructive to your opinions as to whether or not the Prolene® old construction 6-mil mesh used in all of the TVT® devices has pores that are -- any pores that are 1 millimeter in diameter?
MR. THOMAS: Object to the form of the question.
THE WITNESS: There are some pores around 1 millimeter.
QUESTIONS BY MR. ANDERSON:
Q. And would a Prolene® mesh that has pores of pore area right around 1 millimeter be as safe as a pore size of ULTRAPRO™ or VYPRO with pores that are in the 3 to 5 millimeter range in diameter?
MR. THOMAS: Object to the form of the question.
THE WITNESS: No. It is very clear that large pore meshes with 3, 4 millimeters has very, very low risk,

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and it is clear that small pores mesh has higher risk. And biologically, this is true for Prolene® because it bridges all the time. If you look to the textile property -- the textile porosity, you see that the pores are around 1 millimeter. But if you look to the effective porosity, it is quite low. And, therefore, this is consistent.
(Klinge Exhibit 32 marked for identification.)
QUESTIONS BY MR. ANDERSON:
Q. Showing you what we will mark as Klinge Exhibit 32. It's a document that I have previously provided to you.
Do you recall that, Dr. Klinge?
A. Yes.
Q. And if you look at the front page of this PowerPoint, are these the same authors that we looked at in this Moalli, Abramowitch, Feola article that counsel showed you earlier today?
A. I agree.

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Q. And if you turn to the third page of this document, first of all, is the date, May 24, 2013?
A. Yes.
Q. And if you look down into the middle slide on that page under "Material Parameters, Textile and Structural Properties of Implant Materials," what does the sixth point say?
A. The sixth point means that --
Q. What does it say, number 6?
A. Effective porosity.
Q. And under "Biomechanics," does it list the Mühl article that you did with Professor Mühl in 2008?
A. Yes.
Q. From your reading of the Feola, Abramowitch and Moalli article, was this your understanding that this is a group out of Pittsburgh, Pennsylvania?
A. Yes.
(Klinge Exhibit 33 marked for identification.)

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QUESTIONS BY MR. ANDERSON:
Q. One last document. I'm going to show you Klinge Exhibit 33.
Showing you this document that we've marked as Klinge 33. Sorry.
Are you familiar with Christoph Walther?
A. Yes, I know him.
Q. Is this a name that you had mentioned yesterday as someone you had worked with from R&D in Hamburg at Ethicon facilities there?
A. Yes.
Q. And even going back to your work with Ethicon from the late '90s in the development of VYPRO?
A. Yes.
Q. And this is a letter from Christoph Walther to Quentin.
Are you familiar with a Quentin Manley?
A. No, I don't know.
Q. And this second paragraph here is talking about, "This applicant is a German company in Aachen, FEG Textiltechnik, and the inventors are U. Klinge and B. Klosterhalfen, RWTH Aachen, and two peoples from FEG."
Do you see that?
A. Yes, I see it.
Q. And then, "FEG has some products for hernia repair on the market and also for pelvic floor surgery."
Did I read that correctly?
A. That is correct.
Q. "In Germany, these products are distributed through Dahlhausen, a big dealer for medical device."
Do you see that?
A. That is correct.
Q. And then it talks about, "The technology is based on a special material, PVDF."
Do you see that?
A. Yes.
Q. And it says that, "Our material, Ethicon's material, Pronova is comparable to PVDF."
Do you see that?

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A. Yes, I see it.
Q. Is it your understanding that Ethicon has a patent for a PVDF mesh that they filed years ago?
MR. THOMAS: Object to the form of the question.
THE WITNESS: Yes.
QUESTIONS BY MR. ANDERSON:
Q. And you've seen that patent, correct?
A. Yes, I've seen it.
Q. To your knowledge, has Ethicon ever acted upon that patent and tried to produce a surgical mesh with PVDF in it for the pelvic floor or for hernia?
A. I didn't ever get any positive information for this.
Q. And then if we look at the next paragraph down, "In extremely, this patent applications could be a strict restriction for Ethicon to sell implants manufactured from Pronova monofilaments. In my eyes, Pronova monofilaments are extremely good candidate as implant material, very high

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flexibility, low bending stiffness, Y-sterilization -- gamma -- without loss of tensile strength in contrast to polypropylene, long-term stability in human body."

Did I read that correctly?

A. Yes.

Q. And do you know that Christoph Walther is one of the top polymer scientists at Ethicon Norderstedt?

A. Yes.

MR. THOMAS: Object to the form of the question.

QUESTIONS BY MR. ANDERSON:

Q. Did Christoph Walther ever contact you to ask you about working with you on a PVDF mesh for Ethicon's catalog of products for either hernia repair, pelvic organ prolapse repair or stress urinary incontinence repair?

A. No, he didn't do.

Q. Counsel asked you whether or not you were aware of any clinical studies or randomized controlled trials that would look

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at the effect of particle loss of surgical meshes in the tissue.

Do you remember that part of your testimony?

A. Yes.

Q. Do you need a clinical study result, Dr. Klinge, in order to form your opinion that excess polypropylene particles in a human tissue can elicit a greater inflammatory response?

MR. THOMAS: Object to the form of the question.

THE WITNESS: No, there is -- as I tried to express earlier, there is a huge evidence that increase the material, the increase of surface of polymers leads to an increased and intensifying foreign body reaction and with all of the risks.

QUESTIONS BY MR. ANDERSON:

Q. Counsel asked you some questions earlier today regarding the in vivo forces that would be realized underneath a woman's urethra.

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Do you remember that?

A. Yes.

Q. He was asking you for articles that you may have or be aware of that relate to what the estimated forces underneath the bladder may be that the TVT® sling may be subjected to.

Do you remember that part of your testimony?

A. I remember it.

Q. Turning now to Klinge Exhibit 11, which was your expert report.

A. Uh-huh.

Q. I was going to ask you some things counsel did not.

Starting with page 18 of your report and going through page 23 of your report, in those five pages, did you go through an analysis of various literature as well as internal Ethicon documents regarding estimated forces that one could anticipate being on the TVT® sling underneath the bladder neck?

MR. THOMAS: Object to the form

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of the question.

THE WITNESS: Yes.

QUESTIONS BY MR. ANDERSON:

Q. Yes?

A. Yes.

Q. And when you gave counsel a measurement -- strike that.

When you listed to counsel that you could anticipate less than 10 newtons per centimeter in terms of a force that could be placed upon the sling under the bladder neck, is that reflected in the forces that you list on page 23 of your report?

A. Yes, that is a brief summary of all this knowledge collected on these pages.

Q. And after you collected the knowledge that's on these pages, did you then use these figures on page 23 of Klinge Exhibit 11 in order to instruct Professor Mühl as to the forces that you thought he should put on the machine to test the TVT® laser-cut and mechanical-cut meshes?

A. In fact, that was the reason to define the range for the measurements that we

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collected all of this data.
Q. Counsel also had a statement to you, "There are no in vivo studies regarding whether high effective porosity under stress will help improve biocompatibility." Taking that statement out of your 2007 publication with Professor Mühl, "The New Objective Measurements for Porosity."
Do you recall that part of your testimony today?
A. Yes.
Q. Is the concept of effective porosity to allow for proper tissue healing in between the pores?
MR. THOMAS: Object to the form of the question.
THE WITNESS: Yes.
QUESTIONS BY MR. ANDERSON:
Q. And is effective porosity an area that would allow for good tissue healing in pore sizes that are greater than 1 millimeter in all direction?
A. Yes.
Q. Based upon your work in this

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area for the last 20 years, your work in the '90s with BIOMAT and with Ethicon, the development of VYPRO, your publications, your Congresses, all of your work in this field for two decades, do you have an opinion to a reasonable degree of medical certainty as to whether or not the Mühl testing in looking at the 1 millimeter pore diameter of meshes will impact the biocompatibility of that mesh in the tissue?
MR. THOMAS: Object to the form of the question.
THE WITNESS: Yes. I have no doubts about that this is the effect.
QUESTIONS BY MR. ANDERSON:
Q. And do you believe that putting the machine at a 1,000-millimeter limit is based upon all of the work that you've done for the last 20 years, you, Klosterhalfen and the rest of those involved both in Aachen as well as Ethicon in this area of tissue reaction to surgical meshes?
MR. THOMAS: Object to the form of the question.

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THE WITNESS: It is based on the current data that are available, which is known to Ethicon as well.
MR. ANDERSON: That's all of the questions I have for right now, Dr. Klinge.
THE WITNESS: Thank you very much.
MR. ANDERSON: He's got a few.
REDIRECT EXAMINATION
QUESTIONS BY MR. THOMAS:
Q. Dr. Klinge, Exhibit 30, which was the expert report from Piet Hinoul, Mr. Anderson already showed you on page 4 of Exhibit 30 that the weight for the Prolene® mesh is lower than the weight that you typically recorded for the first generation old Prolene®, correct?
A. I tried to calculate there are -- there has been milligram per square centimeters. Usually, it's gram per square meters. I assumed that the usual data of 108-gram per square meter would be 10.8-milligram per square centimeters.

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Q. Do you know whether this is the old Prolene® mesh used in TVT® --
A. It shouldn't be the old one.
Q. It should be the 5-mil hernia repair mesh or some other one?
A. I don't know.
Q. It's -- this is the -- your best interpretation of Exhibit 30, page 4 for the entry of Prolene® is that this is not the first generation Prolene® mesh that you tested and that's used in the treatment of stress urinary incontinence, correct?
A. I just see the name Prolene®. I see this white, and this is inconsistent to what we have seen with other tables where there was Prolene® and -- so this is -- by the way, this is a report from Ethicon.
Q. I know.
A. And I would expect that they indicate clearly what they shared in their table there because this makes a lot of confusion in all the subsequent -- when someone else took over these data there.
Q. Doctor --

A. I just want to say it and have it --
Q. And you did.
A. -- documented.
Q. And you did.
But so I can say it and document it, this is not the first generation Prolene® mesh, correct?
A. It looks like, yes.
Q. It looks like it's not?
A. It looks like it's not.
MR. THOMAS: Thank you. That's all I have.
RECROSS EXAMINATION
QUESTIONS BY MR. ANDERSON:
Q. And even with a later generation Prolene® mesh, they still can't get their pore sizes or Ethicon still chooses not to get their pore sizes above 1 millimeter, correct?
MR. THOMAS: Object to the form of the question.
THE WITNESS: Whatever they presented there as a Prolene® there,

yes, I agree.
MR. ANDERSON: No further questions.
MR. THOMAS: Thank you, Doctor.
MR. ANDERSON: Thank you.
(Deposition concluded at 5:16 p.m.)

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CERTIFICATE

I, CARRIE A. CAMPBELL, Registered Professional Reporter, Certified Realtime Reporter and Certified Court Reporter, do hereby certify that prior to the commencement of the examination, Uwe Klinge was duly sworn by me to testify to the truth, the whole truth and nothing but the truth.

I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the testimony as taken stenographically by and before me at the time, place and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

_____
CARRIE A. CAMPBELL,
NCRA Registered Professional Reporter
Certified Realtime Reporter
Missouri Certified Court Reporter #859
Illinois Certified Shorthand Reporter #084-004229
Notary Public
Dated: December 3, 2013

ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____
Prof. Dr. Med. Uwe Klinge DATE

Subscribed and sworn to before me this _____ day of _____, 20 _____.
My commission expires: _____

Notary Public

ERRATA

PAGE	LINE	CHANGE/REASON

LAWYER'S NOTES

PAGE	LINE